Angela Huskey/DC/USEPA/US	To	Barbara Pace
	cc	
08/16/2006 04:50 PM	bcc	
	Subject	Motions in Human Studies Litigation

Barbara,

Here are the motions filed in the Second Circuit relating to our motion to dismiss.


EPA Motion to Dismiss.wpd


Opposition to Motion to Dismiss.pdf


EPA Reply Support Motion to Dismiss (final).wpd

I'll be in touch later this week to discuss this idea more. Thanks for all your help.
Angela

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UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL	)	
	)	No. 06-0820-AG
Petitioner,	)	(and consolidated case
	)	No. Xxx)
v.	)	
	)	
U.S. ENVIRONMENTAL PROTECTION AGENCY	)	
	)	
Respondent.	)	

RESPONDENT EPA'S MOTION TO DISMISS
FOR LACK OF JURISDICTION (STANDING)

INTRODUCTION

Respondent United States Environmental Protection Agency ("EPA") moves

to dismiss the petitions in Case Nos. 06-0820, 06-1895, 06-2149 and 06-xxxx because each of the these petitioners lacks standing to challenge EPA's rule establishing protections for human subjects in certain research related to pesticides.

The rule challenged in these cases, titled "Protections for Subjects in Human Research" (the "Research Rule"), significantly strengthens and expands the protections for subjects of human research intended for submission to EPA under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). The rule also places additional restrictions on human research conducted or supported by EPA. Finally, the Rule sets new standards for EPA consideration of research conducted prior to the effective date of the rule.

The Natural Resources Defense Council, Pesticide Action Network North America, Pineros y Campesinos Unidos Del Noroeste, Physicians for Social Responsibility – San Francisco, Migrant Clinicians Network and the Farm Labor Organizing Committee, AFL-CIO (collectively "Petitioners") all lack standing to bring their challenge. Neither Petitioners nor their members are injured by the Research Rule. Because the Research Rule sets standards for research involving non-pregnant adults who voluntarily agree to be subjects in human research involving intentional exposures, the Petitioners and their members who oppose such research can avoid any potential injury to themselves by simply not

volunteering to participate. The Research Rule does not subject them to any exposure to pesticides. Further, Petitioners cannot establish standing based upon a speculative chain of events that alleges a hypothetical injury associated with the possibility of higher pesticide tolerance levels that might be established in future EPA proceedings. The speculative chain hypothesized by Petitioners is too attenuated to show imminent injury. In addition, EPA's regulations governing protocols for human research cannot be shown to be the cause of Petitioners' alleged injury. Accordingly, the Court should dismiss the petitions for lack of jurisdiction.

BACKGROUND

I. Regulation of Pesticides Under the FFDCA and FIFRA

A. Regulation of Pesticide Tolerances under the FFDCA

FFDCA section 408(b)(1) authorizes EPA to establish, by regulation, "tolerances" that set the maximum permissible levels of pesticide residues in or on foods. 21 U.S.C. § 346a(b)(1). EPA is to establish regulations setting a tolerance for a pesticide residue or, in appropriate cases, an exemption from the tolerance requirement, only if EPA determines that the tolerance or exemption is "safe." FFDCA section 408(b)(2)(A)(I), 21 U.S.C. § 346a(b)(2)(A)(I). A finding that a tolerance or exemption is safe must be based on "a reasonable certainty that no

harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." FFDCA section 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii).

The FFDCA, as amended by the Food Quality Protection Act ("FQPA"), requires EPA to reevaluate the safety of all pesticide tolerances existing at the time of the FQPA's enactment in 1996, based on a more stringent and scientifically complex evaluation of risk factors. *See* FFDCA section 408(q), 21 U.S.C. § 346a(q). Congress required the reassessment to be completed within ten years of the FQPA's enactment, which period ends on August 3, 2006. *Id.*

B. Regulation of Pesticide Sale, Distribution and Use under FIFRA

Under FIFRA, EPA regulates the sale, distribution, and use of pesticides through a licensing or registration program. Regulation of pesticides under FIFRA and the FFDCA is closely linked. Under FIFRA, EPA may not issue a registration for a pesticide use that has "unreasonable adverse effects on the environment." *See* FIFRA section 3(c)(5) & (7), 7 U.S.C. § 136a(c)(5) & (7). That phrase is defined to include "any unreasonable risk to man or the environment" or "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [FFDCA section

408]." FIFRA section 2(bb), 7 U.S.C. § 136(bb).

Like the FFDCA, FIFRA, contains a requirement that EPA re-examine existing pesticide registrations. FIFRA section 4, 7 U.S.C. § 136a-1. The statute, as amended by the Pesticide Registration Improvement Act of 2003, also prescribes a schedule for "re-registration" of many pesticides. *Id.*

II. Protections for Subjects in Human Research

Human testing to determine the effects of therapeutic drugs and other chemicals, including pesticides, has been undertaken and the results have been submitted to the United States government for many years. To assure the protection of individuals participating in human testing which EPA conducts or supports, EPA implemented the "Common Rule" in 1991, codified at 40 C.F.R. Part 26, which requires human testing conducted or supported by EPA to meet strict ethical and scientific standards.[1/]1 For example, the Common Rule imposes demanding procedures concerning informed and free consent. 40 C.F.R. §§ 26.111(a)(4)-(5), (b), 26.116. In addition, the Common Rule requires, *inter alia*, approval by an Institutional Review Board ("IRB") before human testing begins

[1/] Various agencies involved in human research developed the Common Rule cooperatively. Other agencies have promulgated regulations comparable to EPA's codification of the Common Rule. *See, e.g.*, 56 Fed. Reg. 28,003 (June 18, 1991) (promulgation of regulations by multiple agencies).

and continuing oversight thereafter by the IRB. 40 C.F.R. § 26.103(b).

EPA's recently promulgated Research Rule strengthens and expands protections for both "third party" human research (research that is not conducted or supported by EPA, but is submitted to EPA for consideration) and research conducted or sponsored by EPA. First, with respect to research supported or conducted by EPA, the Research Rule categorically prohibits any research involving intentional exposure to pesticides of pregnant women or children and adopts additional protections beyond those of the Common Rule to pregnant women and children who are subjects in observational research supported or conducted by EPA. 71 Fed. Reg. 6138 (Feb. 6, 2006).

Second, with respect to third-party research, the Research Rule: (1) prohibits new research involving intentional exposure of pregnant women or children intended for submission to EPA under the pesticide laws; (2) extends the provisions of the Common Rule to other human research involving intentional exposure of non-pregnant adults intended for submission to EPA under the pesticide laws; (3) requires the submission to EPA of protocols and related information about human research before it is initiated; and (4) establishes an independent review board to review both proposals for new research and reports of covered human research on which EPA proposes to rely under the pesticide laws.

Id.

Finally, the Research Rule forbids EPA to rely in its actions under the pesticide laws on previously conducted intentional-exposure human research that either involves pregnant women or children or is otherwise considered unethical, except in narrowly defined circumstances. *Id.*

III. Procedural Background

Petitioners, who are groups whose purposes include minimizing human exposures to pesticides, filed four petitions for review of the Research Rule. The Judicial Panel for Multidistrict Litigation consolidated the petitions in this Court.

ARGUMENT

This Court Does Not Have Jurisdiction Over These Petitions Because the Petitioners Lack Standing to Challenge EPA's Issuance of the Research Rule.

Courts must resolve jurisdictional issues before considering the merits of a dispute. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998); *Alliance for Environmental Renewal, Inc. v. Pyramid Crossgate Co.*, 436 F.3d 82, 85 (2d Cir. 2006).

In order to pursue their claims in federal court, the Petitioners must, as a threshold matter, satisfy the requirements for constitutional standing. To meet the Article III requirements for standing, each Petitioner must demonstrate that: (1) it

or one of its members has suffered an "injury in fact" that is actual and imminent, not conjectural or hypothetical;[1/]2 (2) the injury complained of is caused by or fairly traceable to the challenged action of EPA; and (3) it is likely that the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *Lafleur v. Whitman*, 300 F.3d 256, 269 (2d Cir. 2002). The burden is on the Petitioners to demonstrate affirmatively and clearly that they possess sufficient standing to seek the requested relief. *See FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990); *Lafleur*, 300 F.3d at 268.

Petitioners do not have standing to challenge the Research Rule. Neither the organizations nor their members are injured by the Research Rule, and the alleged injury they claim they will suffer is not caused by the Research Rule. Therefore, the petitions should be dismissed.

A. The Petitioners Have Not Suffered an Injury-in-Fact.

To demonstrate injury sufficient for standing, a party must show an "injury-in-fact" -- an "invasion of a legally protected interest which is (a) concrete and particularized" and (b) "actual or imminent, not 'conjectural' or

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[2/] All of the Petitioners are associations. An association has representational standing only if its members would otherwise have standing to sue in their own right. *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977); *N.Y. Public Interest Research Group v. Whitman*, 321 F. 3d 316, 325 (2d Cir. 2003).

'hypothetical.'" *Defenders of Wildlife*, 504 U.S. at 560; *Lafleur*, 300 F.3d at 269. "Abstract injury is not enough," the injury must be "real and immediate." *Los Angeles v. Lyons*, 461 U.S. 95, 101-102 (1983).

1. Petitioners Lack Standing Because the Research Rule Does Not Regulate Them or Their Members.

Petitioners bear a particularly heavy burden to establish standing in this case because the Research Rule does not impose any requirements or obligations upon the Petitioners or their members. *See Lujan*, 504 U.S. at 562. The Research Rule governs the conduct of researchers and provides protections for people who volunteer to participate in research involving intentional dosing of pesticides. Petitioners and their members are opposed to pesticide research using human subjects. They do not conduct research involving intentional exposure of humans to pesticides. They presumably do not volunteer to participate in such research.[1/]3 Thus, Petitioners and their members are not injured by exposure to

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[3/] Even if one of Petitioners' members volunteered to participate in human research, any alleged injury would result from that decision to volunteer and not from the Research Rule. See Jackson-Bey v. Hanslmaier, 115 F.3d 1091, 1095 (2d Cir. 1997) (prisoner lacked standing because any injury he suffered was attributable to his own decision); Public Utility Dist. of Snohomish County v. FERC, 272 F.3d 607, 617 (D.C. Cir. 2001)

pesticide as a result of the EPA requirements for human testing established in the Research Rule that they challenge in this case.[1/]4

Further, Petitioners cannot assert injury arising "from the government's allegedly unlawful regulation (or lack of regulation) of someone else." Lujan, 504 U.S. at 562 (emphasis added);

Lafleur, 300 F.3d at 269 n.2. Therefore, any potential injury to persons who volunteer to participate in the human research cannot support Petitioners' standing.

2. Petitioners' Theory of Injury is Based Upon Speculation and Conjecture That is Insufficient to Establish Standing.

Although the Research Rule has no direct effect on them, Petitioners nonetheless claim that the Research Rule will harm their members by increasing their exposure to pesticides, based upon an extended chain of speculation as to

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(utilities lacked standing because utilities are injured only if they voluntarily chose to participate in regional transmission organization).

[4/] In contrast, this Court found that risks associated with exposure to potentially harmful food and drug products is cognizable as injury for standing purposes. *See Baur v. Veneman*, 352 F.3d 625, 634 (2d Cir. 2003).

future events. *See* Petitioner's Pre-Argument Statements, Part A: Standing and Venue. When courts of appeals consider "any chain of allegations for standing purposes," they reject as "overly speculative those links which are predictions of future events (especially future events to be taken by third parties)." *United Transp. Union v. Interstate Commerce Comm'n*, 891 F.2d 908, 912 (D.C. Cir. 1989). Injury based on a string of future contingent government actions is not "imminent." *Louisiana Envtl. Action Network v. Browner*, 87 F.3d 1379, 1383 (D.C. Cir. 1996) (petitioners' assertions were too remote to establish an imminent and concrete injury because petitioners could not be injured without the occurrence of a subsequent chain of events that might not come to pass). "Where there is no current injury, and the party relies wholly on the threat of future injury, the fact that the party (and the court) can 'imagine circumstances in which [the party] could be affected by the agency's action' is not enough." *Northwest Airlines, Inc. v. FAA*, 795 F.2d 195, 201 (D.C. Cir. 1986) (emphasis in original); *see also Lujan*, 504 U.S. at 566 ("[s]tanding is not 'an ingenious academic exercise in the conceivable'").

Petitioners imagine potential injury based upon conjecture regarding the results of future human research involving intentional dosing and how that data might be used to increase pesticide exposures through future EPA action under

FFDCA and FIFRA. See Complaint, ¶¶ 11-16, *Pesticide Action Network North America, et al. v. U.S. Environmental Protection Agency*, Case No. 3:06-cv-01366-MMC (N.D. Cal. filed February 23, 2006) attached as Exhibit A.[1/]5 Such injury based upon the hypothetical results of future research and subsequent EPA action is too speculative and attenuated to provide a basis for standing. Petitioners' chain of speculation assumes that: (1) a researcher engages in a study involving intentional human dosing of a pesticide that yields data that could support a higher safety level (*e.g.*, one that is arguably less stringent) for the pesticide; (2) EPA determines that the study was conducted ethically and was scientifically valid; (3) EPA relies upon the study in future action to establish a higher safety level under FFDCA or FIFRA; (4) such higher levels would not be supported by other data considered by EPA during the rulemaking; and (5) one of Petitioners' members is then exposed to such higher levels of pesticides.[1/]6

[5/] In addition to the petitions for review pending in this Court, certain Petitioners also filed a challenge to the Research Rule in the United States District Court for the Northern District of California. *Pesticide Action Network North America, et al. v. U.S. Environmental Protection Agency*, Case No. 3:06-cv-01366-MMC (N.D. Cal. filed February 23, 2006). The complaint filed in the district court contains allegations describing certain Petitioners' organizations and the alleged injury they attribute to the Research Rule. Complaint ¶¶ 11-16 (Exhibit A). The complaint asserts that is was filed as "a protective matter, in the event that the Court of Appeals concludes that jurisdiction properly belongs in District Court." Complaint ¶ 7 (Exhibit A).

[6/] In the case of a previously performed study involving intentional human dosing of a pesticide, the speculative chain of injury still involves links two through five above.

This hypothetical chain is analogous to the "multi-tiered chain of speculation" found insufficient for standing in *Louisiana Envtl. Action Network*. In *Louisiana Envtl. Action Network*, the environmental petitioners challenged EPA procedures used to decide whether EPA should approve state rules or programs to implement various air pollution requirements. *Id.* at 1380. The environmental petitioners challenged the procedures because they permitted EPA not to enforce federal requirements upon approval of a states' proposed program, thereby resulting in a potential enforcement gap between the time of EPA approval and the time the state's program became effective. *Id.* at 1382. The court found that this enforcement gap was not imminent injury because it assumed that a state would seek to substitute its program for a federal program, that the state's program will not be effective at the time approval was sought, and that EPA would approve a state's program that was not yet effective. *Id.* at 1383. The court found such speculation to be "too remote a possibility" to establish an imminent injury. *Id.* *See Prestage Farms, Inc. v. Board of Supervisors of Noxubee County, Miss.*, 205 F.3d 265, 268 (5th Cir. 2000) (an injury that depends on the occurrence of a number of uncertain events is too conjectural to provide standing).

In this case, as in *Louisiana Envt'l Action Network*, Petitioners' alleged injury will occur, if at all, only as a result of some potential, future agency action

that would depend upon a number of contingencies. If EPA in the future sets tolerances or safety levels under FFDCA or FIFRA, and if that action adversely impacts Petitioners, Petitioners could seek to challenge that specific future action. That future challenge, assuming other jurisdictional requirements are met, could raise issues arising from EPA's or another party's reliance on data generated using intentional exposure to human test subjects under the Research Rule. *See Louisiana Envt'l Action Network*, 87 F.3d at 1384 (such a future proceeding "will be soon enough to determine the merits of [Petitioners'] claim").

In sum, Petitioners cannot rely for standing on the speculative threat of injury in a future EPA action based upon their ability to imagine circumstances where they could be affected by the results of research involving human exposures. *See Northwest Airlines*, 795 F.2d at 201.

3. Any Alleged Injury to Petitioners' Organizational Interests Are Insufficient to Provide Them With Standing to Challenge the Research Rule.

Petitioners' organizational interests in minimizing pesticide exposures do not provide them a basis to claim injury. An organization suing on its own behalf must meet the same three-part standing test that

applies to individuals. *Irish Lesbian and Gay Organization v. Guiliani*, 143 F.3d 638, 649 (2d Cir. 1998). With respect to injury, the organization must establish:

> [a] concrete and demonstrable injury to the organization's activities – with [a] consequent drain on the organization's resources – constitut[ing] . . . more than simply a setback to the organization's abstract social interests . . . . Indeed, [t]he organization must allege that discrete programmatic concerns are being directly and adversely affected by the challenged action.

Common Cause v. Federal Election Comm'n, 108 F.3d 413, 417 (D.C. Cir. 1997) (quoting *National Taxpayers Union, Inc. v. United States*, 68 F.3d 1428, 1433 (D.C. Cir. 1995)). Further, the injury allegedly suffered by the organization, like an injury to its members, cannot be "'conjectural' or 'hypothetical,'

'remote,' 'speculative,' or 'abstract.'" *National Treasury Employees Union v. United States*, 101 F.3d 1423, 1427 (D.C. Cir. 1996). Instead, it must be "'certainly impending.'" *Id.* (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

For reasons similar to those discussed above in the context of Petitioners' members' standing, Petitioners also lack standing to sue on their own behalf. Petitioners' organizational interests include advocacy for the decreased use of and exposure to pesticides. However, the Research Rule does not "directly and adversely" affect these interests because it does not increase pesticide use or exposure. At best, Petitioners can assert that the Research Rule has the potential to lead to, or allow the consideration by EPA of, research that may, at some future time, frustrate their objectives. However, frustration of an organization's objectives "is the type of abstract concern that does not impart standing." *National Taxpayers Union*, 68 F.3d at 1433. Accordingly, Petitioners' organizational injury is insufficient to satisfy constitutional requirements.

Therefore, these petitions must be dismissed because the

Court lacks subject matter jurisdiction. *Bender v. Williamsport Area School Dist.*, 475 U.S. 534, 541 (1986) (defect in standing is defect in court's subject matter jurisdiction).

B. The Petitioners Cannot Satisfy the Causation Requirements of Standing.

The "causation" element of constitutional standing requires this Court to ask whether it is "substantially probable" that the challenged action of EPA caused the Petitioners' alleged particularized injury. *See Florida Audubon Soc'y v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996) (en banc). To the extent the Court recognizes Petitioners' claims of increased exposure to pesticides as an actual and imminent injury, that injury is not caused by the Research Rule. The Research Rule establishes no new or revised safety levels for pesticides. Further, the Research Rule contains no determination regarding the scientific validity and probative value of future human research involving pesticides.

Petitioners' theory of causation appears to rely on the hypothesis that the Research Rule will prompt future research that will be used in future EPA action to

reduce safety levels. Numerous courts have found this type of causation theory too remote to establish standing. For example, in *Shoreham-Wading River Central School Dist. v. NRC*, 931 F.2d 102, 105 (D.C. Cir. 1991), the petitioners sought to challenge an agency ban on refueling a nuclear reactor by arguing that the ban laid the basis for future agency action that could pose environmental risks. The court observed that, even if it assumed the risks associated with the future action, any injury could not occur until the agency took the future action. *Id.* In other words, even if the ban was a "but for" cause of a future agency action and any resulting risk, the future action will be the operative cause of injury. *Id.* The petitioners in *Shoreham-Wading* could not establish that the environmental risks were fairly traceable to the refueling ban. *See Natural Resources Defense Council v. EPA*, 902 F.2d 962, 976 (D.C. Cir. 1990) (affected parties can contribute to future regulatory action and, if future action is based on poor information, it could be challenged by affected parties).

The same lack of a fairly traceable connection between the Research Rule and Petitioners' injury dooms Petitioners' standing argument here. The most Petitioners can argue is that the Research Rule could lay the basis for research that might be considered in future agency action relating to pesticide safety levels. The link between the Research Rule and any speculation regarding the outcome of

future EPA action on safety levels is too remote for standing.

Further, causation does not exist where injury "depends on the unfettered choices made by independent actors not before the court and whose exercise of broad and legitimate discretion" the courts cannot presume either to control or to predict. *Lujan*, 504 U.S. at 562; *See Garelick v. Sullivan*, 987 F.2d 913, 918-20 (2d Cir. 1993) ("missing link" in causal chain because Medicare beneficiaries could not show that change in Medicare policy would cause physicians to increase beneficiaries' bills). Petitioners' theory of causality contains just such a "missing link" because it fails to account for the fact that independent researchers may or may not choose to engage in research using human subjects that may or may not yield results that support less stringent standards for pesticides to which their members might be exposed. The independent actions of researchers and the regulated community not before this Court break Petitioners' chain of causation. Because the only action taken through the Research Rule is the establishment of more protective standards for subjects of human research, the Research Rule cannot be found to have caused any injury to Petitioners or their members.

CONCLUSION

For these reasons, the Court should dismiss the Petitioners' petitions for lack of jurisdiction.

Respectfully submitted,

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May xx, 2006

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC.,	)	
Petitioner,	)	**No. 06-0820-ag (L)**
	)	No. 06-1895-ag (CON)
v.	)	No. 06-2149-ag (CON)
	)	No. 06-2360-ag (CON)
U.S. ENVIRONMENTAL PROTECTION AGENCY,	)	
Respondent.	)	

PETITIONERS' RESPONSE TO EPA'S MOTION TO DISMISS

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REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 27(b), Petitioners Natural Resources Defense Council, Pesticide Action Network North America, Pineros y Campesinos Unidos del Noroeste, Physicians for Social Responsibility – San Francisco, Farm Labor Organizing Committee, AFL-CIO, and Migrant Clinicians Network request oral argument.

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INTRODUCTION

Petitioners bring this suit to invalidate an Environmental Protection Agency ("EPA") rule that unlawfully allows the Agency to use scientifically and ethically flawed human toxicity experiments as the basis for relaxing pesticide health protections. These experiments include studies, funded by the chemical industry in an effort to justify weaker health standards, in which humans are intentionally administered pesticides to study the chemicals' toxic effects. Petitioners' members are farmworkers, farmers, medical professionals, and consumers of pesticide-contaminated foods who are exposed to dangerous pesticides on the job, in their homes, and on their dinner tables. They are directly harmed by EPA's human testing rule because EPA is relying on that rule to raise allowable human exposure levels for these pesticides. The increase in pesticide exposures that Petitioners' members face due to EPA's weakening of health standards is precisely the sort of harm that this Court has repeatedly recognized as satisfying Article III.

BACKGROUND

I. Statutory and Regulatory Background

EPA establishes limits on human exposure to pesticides under several statutes, including the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136 *et seq*., and section 408 of the Federal Food, Drug, and Cosmetics Act ("FFDCA"), 21 U.S.C. §§ 346a. Under FIFRA, EPA may

register a pesticide for sale only if the chemical will not cause an "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. §§ 136(bb), 136a(c)(5)(C). Under the FFDCA, EPA sets "tolerances" – allowable levels of pesticide residue on food – at a level that the Agency asserts is safe. *See* 21 U.S.C. §§ 331(a), 342(a)(2)(B), 346(a)(1) & (2), 346a(b)(2)(A)(i).

In 1996, Congress amended these statutes to require EPA to establish exposure limits that are more protective of human health. *See* Food Quality Protection Act of 1996 ("FQPA"), Pub. L. No. 104-170, 110 Stat. 1489 (1996). Of significance here, Congress required that, in setting pesticide tolerances, EPA apply an additional default "tenfold margin of safety . . . for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity in infants and children." 21 U.S.C. § 346a(b)(2)(C). Congress also required EPA to complete pesticide tolerance reassessments and associated re-registration decisions, using the new FQPA health standards, by August 2006, and to complete other pesticide re-registration decisions, for non-food-use pesticides, by October 2008. *See* 21 U.S.C. § 346a(q) (FFDCA deadlines); 7 U.S.C. § 136a-1(g) (FIFRA deadlines).

II. Human Toxicity Experiments and Congressional Response

Following enactment of the FQPA, pesticide manufacturers became concerned that the law's stricter standards would force EPA to restrict the use of and market for their pesticides. Several of these manufacturers began to submit to EPA the results of intentional toxicity experiments on humans. Koh Decl., Ex. B at 3. The manufacturers have claimed that these experiments show that humans are less susceptible to the pesticides than EPA had thought based on animal data.

Two years after the FQPA's enactment, EPA issued a statement that it was "deeply concerned that some pesticide manufacturers seem to be engaging in health-effects studies on human subjects as a way to avoid more protective results from animal tests under the new Food Quality Protection Act." Koh Decl., Ex. A. In 2004, the National Academy of Sciences issued an exhaustive report on these intentional human dosing experiments. As the Academy reported:

> [S]oon after enactment of the FQPA, companies began submitting to EPA studies in humans that were intended to demonstrate that for certain chemicals the 10-fold interspecies uncertainty factor could be reduced or eliminated. If the studies and the reasoning behind them were accepted by EPA, they could have the effect of at least partially offsetting the FQPA's new safety factor for children . . . and increasing the likelihood that existing tolerances, and thus markets, for the pesticides would be maintained.

Koh Decl., Ex. B, at 3; *see also* 71 Fed. Reg. 6161 (Feb. 6, 2006) (human testing rule preamble) (similar); 151 Cong. Rec. H7021 (July 28, 2005) (daily ed.); Finkel Decl., ¶¶ 39-40; Solomon Decl., ¶ 11.

Critical of EPA's existing standards for such experiments, the National Academy proposed that EPA adopt seventeen specific recommendations to ensure that the conduct and use of such studies met rigorous scientific and ethical standards. Koh Decl., Ex. B, at 7-20, 66-67. In 2005, however, EPA resumed its use of human toxicity dosing experiments without adopting the National Academy's recommendations. *See* 70 Fed. Reg. 6661, 6666 (Feb. 5, 2005).

Congress responded to EPA's resumed reliance on human dosing experiments by enacting a moratorium on EPA's consideration or use of such tests. *See* Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, § 201, Pub. L. No. 109–54, 119 Stat. 499, 532. Congress also required EPA to issue a rule to govern the conduct and use of such studies that "shall not permit the use of pregnant women, infants or children as subjects" and "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation." *Id.*

III. EPA's Human Testing Rule

In February 2006, EPA issued its human testing rule. 71 Fed. Reg. 6138 (Feb. 6, 2006). In the merits of this action, Petitioners contend that this rule allows the pesticide industry to conduct, and EPA to rely upon, intentional human dosing toxicity experiments that do not meet the rigorous scientific and ethical standards

required by Congress, including the National Academy's proposed scientific and ethical standards and the ethical requirements of the Nuremberg Code, issued during the Nazi medical doctors' war crimes trial, following World War II.[1]

Petitioners' concern has proven well founded. In the first few months of the human testing rule's operation, EPA has already proposed to rely on a number of scientifically and ethically flawed human experiments to set exposure limits that are higher than EPA would have set in the absence of the flawed human studies. *See, e.g.*, Koh Decl., Exs. C at 9, D; Solomon Decl., ¶¶ 12, 21-22, 30-31, 39, 40; Finkel Decl., ¶¶ 9, 11, 38; Reeves Decl., ¶¶ 8-9. EPA's review board, applying the loose standards of EPA's rule, has recently approved EPA's proposed use of these human experiments to for at least seven pesticides. *See* Koh Decl., Ex. D.[2] EPA recently finalized its action using a higher exposure level for at least one of these pesticides. *See* Koh Decl., Exs. H, J; Solomon Decl., ¶ 30. EPA expects to

[1] Petitioners contend, for example, that EPA's rule has unlawfully allowed the Agency to rely on human experiments in which there were so few human subjects that the study lacked enough statistical power to demonstrate adverse health effects that might occur – and that this reliance is resulting in EPA raising human exposure limits. *See, e.g.*, Finkel Decl., ¶¶ 28, 42, 43; Solomon Decl., ¶¶ 12, 13. The National Academy shared this concern, for it recommended that EPA promulgate specific criteria for statistical validity of human experiments. *See* Koh Decl., B at 7, 66. EPA's failure to establish such criteria – which has allowed the Agency to rely on scientifically flawed research to increase exposure limits – is one of the bases for Petitioners' challenge.

[2] These pesticides include: aldicarb, amitraz, chromium, DDVP, methomyl, oxamyl, and sodium cyanide. *See* Koh Decl., Ex. D; http://www.epa.gov/osa/hsrb/files/secondtdraft61406.pdf (visited Aug. 3, 2006) (final draft human studies review board report for May 2-3, 2006 meeting).

finalize its proposals for the other pesticides imminently, *see, e.g.*, Koh Decl., Ex. I, if it has not already,[3] and faces a statutory deadline to do so, *see supra*, at 2. But for the human testing rule, EPA could not use these studies to weaken standards.

Petitioners bring this challenge because EPA is relying on its rule to raise allowable pesticide exposure limits to Petitioners' and their members' detriment. Contrary to EPA's suggestion (Mot. at 9), this case does not seek to halt all pesticide research involving human beings. Rather, this case challenges an EPA rule under which the Agency is relying on scientifically flawed and ethically deficient human dosing toxicity experiments to raise exposure limits in a way that will cause Petitioners and their members harm.

ARGUMENT

I. Article III Standing

The standing doctrine, one aspect of the Article III "case or controversy" requirement, "determines whether the claimant may properly invoke the jurisdiction of the federal courts to determine the merits of the underlying dispute." *LaFleur v. Whitman*, 300 F.3d 256, 268 (2d Cir. 2002) (citation and internal quotation marks omitted). To establish standing, a plaintiff must allege: (1) "an

[3] On August 2, 2006, EPA announced the completion of tolerance reassessment decisions for all but five pesticides. *See* EPA Press Release, *http://yosemite.epa.gov/opa/admpress.nsf/7c02ca8c86062a0f85257018004118a6/b12a35eea962826a852571bd0069ac8f!OpenDocument* (visited Aug. 3, 2006). As of the August 3, 2006 filing date of Petitioners' brief, not all of those decisions were publicly available.

'injury in fact'" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical"; (2) a "causal connection between the injury and the conduct complained of"; and (3) a likelihood "that the injury will be redressed by a favorable decision." *Bennett v. Spear*, 520 U.S. 154, 167 (1997). In addition, an organization may sue on behalf of its members if:

> (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purposes; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

Hunt v. Washington State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977).

II. Petitioners' and Their Members Suffer Well-Recognized Injuries Sufficient to Satisfy Article III

A. Petitioners' Members Increased Exposure to Toxic Chemicals Presents a Non-Speculative Article III Injury

Petitioners' members include farmworkers who apply and are exposed to pesticides in the fields where they work, families whose houses are surrounded by and downwind of fields sprayed with pesticides, and consumers who eat pesticide-sprayed food as part of their regular diet. *See* Decls. of Stacey Nordgren, ¶¶ 4-5; Ramon Ramirez, ¶¶ 9-14; Baldemar Velasquez, ¶¶ 5-6; Harjinder S. Gill, ¶¶ 4-9; Rhonda Roff, ¶¶ 8-12; Karen Mountain, ¶ 15. EPA's human testing rule will increase these persons' exposure to pesticides (and exacerbate associated health risks and uncertainty) because it will cause EPA to raise pesticide exposure limits.

This injury is not speculative; it has begun. Such an injury falls well within the class of harms this Court has found sufficient for Article III standing.

In *LaFleur v. Whitman*, 300 F.3d 256 (2d Cir. 2002), this Court held that exposure to a pollutant from a facility adjacent to the plaintiffs workplace was "an 'injury in fact' sufficient to confer standing," even though the exposure fell below EPA's health-based regulatory standards. *Id.* at 270. This Court reasoned that even "potentially adverse" effects could satisfy Article III because "[t]he injury-in-fact required for standing 'need not be large, an identifiable trifle will suffice.'" *Id.*

Similarly, in *New York Public Interest Research Group v. Whitman*, 321 F.3d 316 (2d Cir. 2003) ("*NYPIRG*"), this Court held that "allegations about the health effects of air pollution and of uncertainty as to whether the EPA's actions expose [the plaintiff's members] to excess air pollution are sufficient to establish injury-in-fact, given that each lives near a facility subject to [the challenged agency action]." *Id.* at 325. Under *NYPIRG*, even "health-related *uncertainty*" from an EPA failure to enforce regulatory standards constitutes Article III injury. *Id.* (emphasis in original); *see also id.* at 326 (same).

Likewise, in *Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003), this Court recognized that "threatened harm in the form of an *increased risk* of future injury may serve as injury-in-fact for Article III standing purposes." *Id.* at 633 (emphasis

added); *see also id.* at 628.[4] The *Baur* Court allowed the plaintiff to proceed with a challenge to a federal livestock regulation that allegedly would increase his risk of exposure to "mad cow disease," even though at that time this disease had never been found in the United States. *Id*. at 627-28, 633-35, 641-42.

With discussion of this precedent, EPA relies entirely on out-of-context quotes from cases in other jurisdictions to assert that Petitioners' injuries are too speculative to satisfy Article III. There is nothing speculative about the harms posed by exposure to these pesticides. These pesticides can cause severe neurological, developmental, behavioral, and other disorders in humans. *See* Solomon Decl., ¶¶ 12, 17, 24, 32; Reeves Decl., ¶¶ 6-10. EPA does not deny that increased exposure to such chemicals is itself an Article III injury. Mot. at 12.[5]

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[4] The principle that increased risk of future harm constitutes Article III injury is not only common sense – people routinely buy insurance to mitigate risks of future harm – it is also deeply established in precedent of this and other Circuits. *See e.g.*, *Central Delta Water Agency v. United States*, 306 F.3d 938, 947-948 (9th Cir. 2002); *Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001); *Johnson v. Allsteel, Inc.*, 259 F.3d 885, 888 (7th Cir. 2001); *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 160 (4th Cir. 2000); *Louisiana Envtl. Action Network v. EPA*, 172 F.3d 65, 67-68 (D.C. Cir. 1999); *Walters v. Edgar*, 163 F.3d 430, 434 (7th Cir. 1998), *cert. denied*, 526 U.S. 1146 (1999); *Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1234-35 (D.C. Cir. 1996); *but cf. Natural Resources Defense Council v. Environmental Protection Agency*, 440 F.3d 476, 484 (D.C. Cir. 2006) ("[T]he law of this circuit is that an increase in the likelihood of harm may constitute injury in fact only if the increase is sufficient to 'take a suit out of the category of the hypothetical.'").

[5] The precise level of risk posed by such exposure is not itself an Article III question, but a question on the merits. *Baur*, 352 F.3d at 642-43; *cf. Havens Realty*

EPA's argument seems instead to be that the Agency's human testing rule will not increase pesticide exposures, or at least that the risk of such exposures is "speculative." Mot. at 11. EPA seems to be suggesting either that researchers will not engage in human experimentation, or that the results of such experiments will not be submitted as support for relaxing pesticide health standards, or that EPA will reject the experiments as scientifically or ethically invalid. Mot. 11-12.

EPA's argument suffers a fundamental flaw: The events EPA labels "speculative" have, for the most part, already occurred and additional, similar actions are imminent. Pesticide manufactures have conducted and submitted to EPA numerous intentional human dosing pesticide toxicity experiments that purportedly support a reduction in health protections. *See* Koh Decl., Exs. A, B at 3. EPA has proposed to rely on a number of these studies to increase allowable exposure levels over the levels EPA would have set absent the human studies. *See* Solomon Decl. 21, 31, 39-40; Finkel Decl. ¶¶ 37, 38; *see also id*. at 30-36, 39-40; Koh Decl., Exs. E-G. EPA's review board, applying EPA's rule, has approved EPA's proposed use of human experiments for at least seven of these pesticides. *See* Koh Decl., Ex. D. EPA has recently finalized a higher exposure limit for at least one of these pesticides, based on a scientifically unsound human study, and is on the verge of finalizing exposure limits for several other pesticides based on

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Corp. v. Coleman, 455 U.S. 363, 379 (1982) (holding that a "perceptibl[e]" injury satisfied Article III).

similarly suspect experiments. *See* Solomon Decl., ¶¶ 27-31; Koh Decl., Exs. H, J; *cf. Baur*, 352 F.3d at 637 n.11 ("[P]ost-filing events may confirm that a plaintiff's fear of future harm is reasonable.").

EPA's suggestion that these events are "speculative" is perplexing.[6] As recently as June 2006, EPA relied on its human testing rule to issue a regulatory decision for dichlorvos ("DDVP") – a neurotoxin and potential carcinogen derived from a World War II-era nerve agent – that increases several food tolerances for the chemicals. *See* Solomon Decl. ¶¶ 24-25; Koh Decl., Exs. E & H. Notably, this EPA action set the acceptable dose for the thirty-day human exposures as much as *ten*-times higher than it would have without the human data. *See* Solomon Decl., ¶ 31; Koh Decl., Ex. E.

Relying on its human testing rule, EPA has also announced a higher acceptable exposure level for aldicarb, a neurotoxic cholinesterase inhibitor, than it would have set without the human study. *See* Solomon Decl., ¶¶ 17, 21. EPA new exposure limit is three-fold higher as a result of its consideration of the human experimental data. *See id.*; Finkel Decl., ¶ 38. EPA has announced that it will finalize this action in September 2006. *See* Koh Decl., Ex. I.

[6] EPA has a history of relying on human studies to set less protective standards. For example, before Congress restricted EPA's consideration of such studies, the phosphine industry used a human study on a handful of Chinese workers to lobby EPA to maintain an exposure limit ten times higher than the Agency was proposing – and apparently, EPA did just that. *See* Finkel Decl., ¶ 37.

EPA has also relied on a defective human study to set higher exposure limits for the neurotoxin amitraz. This spring, EPA proposed to its review board to adopt an acute and chronic oral dose of 1.25 micrograms/kg/day. *See* Solomon Decl., ¶ 39. These proposed human exposure limits are as much as three-fold and five-fold higher than EPA would have calculated based on animal studies. *See id.* at 39, 40; Koh Decl., Ex. F. Applying EPA's human testing rule, the Agency's review board has approved use of the human study. Koh Decl., Ex. D. As of August 2, 2006, EPA considers its action on this pesticide final. *See* Koh Dec., Ex. J; *see also* http://yosemite.epa.gov/opa/admpress.nsf/7c02ca8c86062a0f85257018004118a6/b12a35eea962826a852571bd0069ac8f!OpenDocument (visited Aug. 3, 2006) (EPA press release listing the only pesticides for which tolerances have not been reassessed).

EPA's decisions increasing allowable human exposure levels will directly increase pesticide use and exposure over the levels that would occur had EPA adopted more protective standards. *See* Finkel Decl., ¶¶ 41-44; Solomon Decl., ¶¶ 21-22, 31, 39-40. After all, the pesticide companies are sponsoring these studies for the purpose of justifying less stringent health standards so that they can sell more pesticides. *See supra*, at 3. The resulting increase in use will raise Petitioners' members' exposure and exacerbate associated their health risks and

uncertainty. *See* Solomon Decl., ¶¶ 11, 41-44; Finkel Decl., ¶¶ 15, 16, 22, 23, 31, 40; Roff Decl, ¶¶ 11-13; Gill Decl., ¶¶ 5-9.

This Court's precedent does not, in any event, require Petitioners to show increased exposure has already occurred to establish standing. On the contrary, a *risk* of increased exposure to a known toxin, or an increased *uncertainty* regarding the health effects of exposure, satisfies Article III. *See Baur*, 352 F.3d at 634 n.8 (holding that the standing doctrine does not "distinguish between uncontested exposure to a potentially harmful substance" and "potential exposure to an undisputedly dangerous contaminant"); *NYPIRG*, 321 F.3d at 325 (holding that "health-related *uncertainty*" suffices to establish Article III injury) (emphasis in original); *cf. Rockefeller v. Powers*, 74 F.3d 1367, 1376 (2d Cir. 1996) (holding, in an Equal Protection Clause challenge to a ballot access restriction, that the plaintiffs "need not establish that, absent the current rule, they *necessarily* would see more candidates on their ballot" if "the rule decreases the likelihood that they have choices among delegates").

Petitioners plainly meet these standards. Indeed, "the potential harm" from EPA's human testing rule, is far more certain here than in *Baur*, where this Court allowed the plaintiff to proceed with a challenge to a regulation based on an alleged probability of exposure to a disease that had not, at the time, yet even been found in this country. *See* 352 F.3d at 627-28, 633-355, 641-42. Petitioners'

members here include farmworkers exposed to pesticides on the job; families who live in homes surrounded by and downwind of fields sprayed with pesticides; and individuals who eat pesticide-sprayed produce and foodstuffs. *See supra*, at 7; *see also* Solomon Decl., ¶¶ 15-16. These individuals are routinely exposed to pesticides in their daily lives. As in *LaFleur*, they have "no choice but to breath the air where [they] live[] and work" or to eat the food on their table, and will "undoubtedly" experience "increased levels" of exposure "whenever the wind blows . . . in [their] direction." *LaFleur*, 300 F.3d at 270.[7]

The out-of-Circuit cases on which EPA relies are not to the contrary. In each, the plaintiff's assertion of a future injury depended on a speculative chain of possibilities unsupported by evidence that the events were likely to occur. *See Louisiana Envtl. Action Network v. Browner*, 87 F.3d 1379, 1380, 1383-84 (D.C. Cir. 1996) (rejecting petitioners' standing to challenge an EPA rule that allegedly could create an "enforcement gap" where the petitioners had not shown that such an enforcement gap was likely to occur, let alone that it would occur where petitioners' members lived); *Northwest Airlines, Inc. v. Federal Aviation Admin.*, 795 F.2d 195, 201 (D.C. Cir. 1986) (rejecting the plaintiff airline's challenge to an

[7] *Bennett v. Spear*, 520 U.S. at 167-68, disproves EPA's assertion (Mot. at 8-9) that Petitioners lack standing if they are not themselves among those who are regulated by the human testing rule; the question is not whether the rule regulates Petitioners, but whether it injures them.

FAA determination that a former pilot was "fit to fly" absent any allegation that the former pilot had been hired by any other airline, let alone that he would fly the same routes as the plaintiff airline); *Prestage Farms, Inc. v. Noxubee County*, 205 F.3d 265, 268 (5th Cir. 2000) (rejecting hog producer's challenge to local environmental rule absent any showing that the rule would apply to operations in which the producer had a legally recognized interest). The same is not true here.[8]

It is fact, not speculation, that EPA has already begun to set public health standards for pesticides, to which Petitioners' members are exposed, at levels that are less protective than EPA would have set but for the human testing rule. The increase in pesticide exposure caused by EPA's human testing rule is more than sufficient to satisfy Article III.

B. Petitioners' Organizational Injuries Satisfy Article III

Petitioners sue not only to protect their members from increased exposure to pesticides, but also to protect their own economic interests in responding to pesticide incidents affecting those they represent. These economic and

[8] EPA's other case, *United Transportation Union v. Interstate Commerce Commission*, 891 F.2d 908 (D.C. Cir. 1989) ("*UTU*"), appears to have held that a claim of future injury is *always* "overly speculative" under Article III. *See id*. at 912. Such a theory could not survive *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1991), which acknowledged the potential sufficiency of future injury, and conflicts with the decisions of this Court discussed above. Not even the D.C. Circuit itself today follows *UTU*'s theory. *Compare Louisiana Envtl. Action Network v. EPA*, 172 F.3d 65, 67-68 (D.C. Cir. 1999).

organizational interests are plainly sufficient to satisfy Article III. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982).

Two of Petitioners, Pineros y Campesinos Unidos del Noroeste ("PCUN") and Farm Labor Organizing Committee, AFL-CIO ("FLOC"), are labor unions that collectively represent almost 20,000 farmworkers who labor in fields sprayed with pesticides. *See* Ramirez Decl. ¶¶ 2, 9, 11, 12 ; Velasquez Decl. ¶¶ 8, 13. Petitioner Migrant Clinicians Network ("MCN") represents more than 5,000 medical doctors, nurses, and other clinicians who provide care to approximately 15 percent of the estimated 4.17 million migrant and seasonal farmworkers and their dependents in the United States. *See* Mountain Decl. ¶¶ 1-3. FLOC and PCUN expend economic resources to investigate and respond to pesticide incidents that harm their members; MCN expends resources providing training to clinicians to enable them to respond to such incidents. *See* Ramirez Decl. ¶¶ 7, 11, 14; Velasquez Decl. 8, 13; Mountain Decl. ¶¶ 4-5, 8, 11-13. EPA's contention that Petitioners have only "organizational interests ... [in] advocacy for the decreased use of and exposure to pesticides," *see* Mot. at 15, ignores these interests.

The harm that Petitioners suffer as a result of investigating and responding to additional pesticide poisoning incidents, or in preparing clinicians to treat the

victims of these exposures, is a well-recognized Article III injury.[9] *See Havens*, 455 U.S. at 379; *cf. Sierra Club v. Morton*, 405 U.S. 727, 737 (1972) (recognizing that economic harm satisfies Art. III). Moreover, FLOC, PCUN, and MCN each represent literally thousands of individuals who (or whose clients) face the prospect of increased pesticide exposure. The chance that one these organizations will expend resources to respond to the health effects of such increased pesticide exposure is not the risk to any one member, but the *aggregate* risk that one of their members will face such exposure and harm. The risk to FLOC, for example, is that *any one* of its 12,000 members in several states will be injured due to increased pesticide use or exposure. Hundreds of such acute poisoning incidents already occur among farmworkers every year in just a single state, *see* Reeves Decl., ¶¶ 6-9; nationally, the totals are presumable far higher. When such an injury occurs to even a single union member due to higher exposure levels resulting from

[9] Petitioner MCN also faces a separate type of injury by virtue of its status as an Institutional Review Board ("IRB") for human research on migrant and seasonal farmworkers. The purpose of MCN's IRB is to assure that human research uses scientifically and ethically valid research protocols. MCN's IRB strives to uphold the highest ethical and scientific standards to protect migrant workers and other human subjects. *See* Mountain Decl. ¶ 14. EPA's human testing rule establishes prospective requirements for IRB approval of certain intentional human dosing toxicity studies for pesticides. Petitioners contend, on the merits, that EPA's rule illegally establishes IRB-approval standards which are inconsistent with the Nuremberg Code and the recommendations of the National Academy of Sciences. If this claim is correct, EPA's rule places MCN in the untenable position of implementing regulatory approval standards that violate recognized national and international scientific and ethical norms, including the norms of the Nuremberg Code.

EPA's action, FLOC will expend resources to investigate and respond. The resulting organizational injuries satisfy Article III.[10]

III. Petitioners' Injury Is Fairly Traceable to EPA's Human Testing Rule

EPA's human testing rule unlawfully authorizes the Agency to rely upon the results of scientifically and ethically flawed human pesticide experiments to set allowable pesticide exposure levels, or "reference doses," that are less protective than the Agency would otherwise set. That rule lifted the congressional moratorium on EPA's consideration of human toxicity experiments in setting pesticide health standards. EPA is now relying on its rule to weaken pesticide standards. Petitioners' and their members' injury from the resulting increase in allowable pesticide exposures is thus "fairly traceable" to, and thus caused by, *Bennett*, 520 U.S. at 168, EPA's rule.[11]

EPA's present theory of causation – that "causation" is missing whenever an agency merely authorizes the action that causes an injury – cannot be reconciled with *Baur*. The *Baur* Court held that "if the alleged risk of disease transmission

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[10] These interests are plainly "germane," *Hunt*, 432 U.S. at 343, to Petitioners' purposes. *See, e.g.*, Mountain Decl., ¶ 4; Trujillo Decl., ¶ 4, Ramirez Decl., ¶ 3; Reeves Decl., ¶ 3; Velasquez Decl., ¶ 3; *see generally National Lime Assn. v. Environmental Prot. Agency*, 233 F.3d 625, 636 (D.C. Cir. 2000) (holding that the "germaneness" standard is "undemanding") (internal quotation marks omitted).

[11] EPA does not dispute that Petitioners' injury is redressable under Article III. Congress barred EPA from relying on these human experiments until EPA issued its human testing rule. 119 Stat. 532. Under that rule, EPA is now using the results of such experiments to lower health standards. Petitioners seek invalidation of the rule.

from downed livestock qualifies as a cognizable injury-in-fact then [the plaintiff's] injury is fairly traceable to [the defendant agency's] decision to permit the use of such livestock for human consumption." *Baur*, 352 F.3d at 632 n.6. This holding is not only binding; it is correct.

As the Supreme Court admonished in *Bennett v. Spear*, 520 U.S. at 168-69, the Article III causation standard does not require that "the defendant's actions are the very last step in the chain of causation." Indeed, as *Bennett* itself demonstrates, even where injury is inflicted by an independent actor, that injury may be "fairly traceable" to the defendant's influence. *Id.* To meet this causation test, Petitioners need not show that EPA's human testing rule is the sole cause of their injury. *See Public Interest Res. Group of New Jersey v. Powell Duffryn Terminals, Inc.*, 913 F.2d 64, 72 (3d Cir. 1990). Petitioners need only show that "an increased risk of future injury," *Baur*, 352 F.3d at 633, is "fairly traceable," *Bennett*, 520 U.S. at 168, to EPA's human testing rule. This they have done.

CONCLUSION

For these reasons, EPA's motion to dismiss should be denied.

August 3, 2006

Respectfully Submitted,

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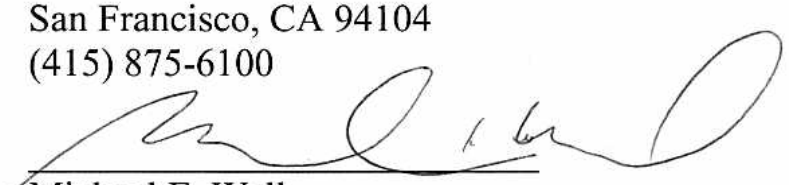
By: 

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that he is an employee in the San Francisco Office of the Natural Resources Defense Council, 111 Sutter Street, 20th Floor, San Francisco, CA, 94104; is a person of such age and discretion to be competent to serve papers; and that on August 3, 2006 he caused a true and correct copy of the foregoing:

- Petitioners' Response to EPA's Motion to Dismiss
- Petitioners' Corporate Disclosure Statement
- Declarations of Stacey Justus Nordgren, Karen Mountain, Rhonda Roff, Margaret Reeves, Ph.D., Harjinder S. Gill, Baldemar Velasquez, Ramon Ramirez, Gina Solomon, Beth Koh, Adam Finkel, and Gina Trujillo

to be placed in a prepaid or postpaid envelope addressed to the persons hereinafter named, at the places and addresses stated below, which are the last known addresses, and by either delivering said envelope to Federal Express for overnight delivery or depositing said envelope and contents in the United States Mail at San Francisco, California, or by facsimile, e-mail, or hand delivery, as stated below:

Via Federal Express:

Alan D. Greenberg
U.S. Department of Justice
Environmental Defense Section
1961 Stout Street, 8th Floor
Denver, CO 80294

Dated: August 3, 2006

Michael Wall

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL	)	
	)	**No. 06-0820-ag (L)**
Petitioner,	)	
		and consolidated petitions
	)	Case No. 06-1895-ag (CON)
v.		
	)	Case No. 06-2149-ag (CON)
	)	Case No. 06-2360-ag (CON)
U.S. ENVIRONMENTAL PROTECTION AGENCY	)	
	)	
Respondent.	)	

RESPONDENT EPA'S REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF JURISDICTION (STANDING)

INTRODUCTION

In its motion to dismiss, Respondent United States Environmental Protection Agency ("EPA") established that each of the petitioners in Case Nos. 06-0820, 06-1895, 06-2149 and 06-2360 lacks standing to challenge EPA's rule establishing protections for human subjects in certain research related to pesticides (the "Research Rule"). In response, Petitioners present several declarations in an effort to establish injury and causation, and all are based upon risks associated with an increased exposure to pesticides. Significantly, none of these alleged increased risks are associated with the only exposure to pesticides addressed in the Research Rule: as a human subject participating in an intentional dosing research study.

As explained in EPA's motion, the Research Rule sets standards for research involving non-pregnant adults who voluntarily agree to be subjects in human research involving intentional exposures. Petitioners have not claimed that any of their members volunteer to participate in this research. Therefore, the Research Rule does not subject them to any exposure to pesticides.

The injury that Petitioners rely on for standing is a potential increase in exposure to pesticides associated with separate, subsequent administrative actions taken by EPA. This "risk" – that the challenged action may affect the data considered in future agency decisions addressing exposure to harmful products or substances – is not a risk previously recognized by this or other courts as injury

sufficient to establish standing. Further, the Research Rule cannot be shown to be the cause of Petitioners' alleged injury. Accordingly, the Court must dismiss the petitions for lack of jurisdiction.

ARGUMENT

A. The Petitioners Have Not Suffered an Injury-in-Fact Because the Research Rule Does Not Expose Petitioners' Members to Pesticides.

Petitioners argue that this Court has recognized that exposure to increased levels of hazardous substances or products resulting in an increased risk of injury is sufficient to establish injury-in-fact for Article III standing purposes. Petitioners' Response ("Pet. Resp.") at 8-9; *See Baur v. Veneman*, 352 F.3d 625, 633-34 (2d Cir. 2003). However, Petitioners' members will not be exposed to increased levels of pesticides because of the Research Rule. The only exposures to pesticides attributable to the Research Rule are those experienced by volunteers who give their informed consent to be subjects in human testing. Petitioners do not claim that any of their members are exposed to pesticides as a result of being subjects in intentional dosing studies. Thus, the Research Rule does not expose Petitioners' members to pesticides at all, much less increase their exposure.

This fact distinguishes this challenge to the Research Rule from the several cases that Petitioners discuss in their response. *See* Pet. Resp. at 8-9. In each of these cases, the challenged agency action exposed petitioners to pollutants or harmful products. For example, in *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002), the challenged action allowed issuance of an air emission permit to a

facility that emitted sulfur dioxide. The Court found that the petitioner, who worked adjacent to the facility, would likely breathe those emissions, so would likely be exposed to sulfur dioxide. *Id.* at 270. In *New York Public Interest Research Group v. Whitman*, 321 F.3d 316, 325 (2d Cir. 2003), the challenged EPA decision regulated emissions of air pollutants from several facilities. The petitioners' members resided in close proximity to the regulated facilities, and the Court found standing based upon potential exposure to excess air pollution. *Id* at 325. Finally, in *Baur v. Veneman*, the challenged livestock regulation authorized human consumption of downed cattle, which had a higher chance of transmitting disease. *Baur*, 352 F.3d at 628. Mr. Baur ate beef, which could have come from downed cattle as the result of the regulation, and the Court therefore found standing based on exposure to potentially unsafe food products. *Id.* at 636, 640.

In contrast, Petitioners are not claiming that any of their members inhale or ingest pesticides in human research studies. Thus, Petitioners and their members are not injured by exposure to pesticides as a result of the Research Rule.

2. Petitioners' Members' Alleged Injuries Cannot Occur Until and Unless EPA Takes Subsequent Administrative Action That Increases Pesticide Safety Levels.

Petitioners cannot base standing on the increased "risk" that study data not prohibited by the Research Rule will be used in an extended chain of contingent

government actions to increase their exposure to pesticides. Although Petitioners attempt to characterize this injury as an increased risk of harm due to higher pesticide exposures, the "risk" they actually face is an increased chance that future agency action will result in increased exposures to pesticides. This is not an actual, concrete injury.

Courts have rejected, for standing purposes. injury attributable to the increased likelihood of subsequent adverse government decisions. In such cases, the injury does not occur until the future government decision is made. *See Louisiana Envtl. Action Network v. Browner*, 87 F.3d 1379, 1383 (D.C. Cir. 1996) ("*LEAN*") (petitioners' assertions too remote to establish imminent and concrete injury because petitioners could not be injured without occurrence of subsequent chain of events that might not come to pass); *Shoreham-Wading River Central School Dist. v. NRC*, 931 F.2d 102, 105 (D.C. Cir. 1991) (even if court assumes risks associated with future agency action, any injury could not occur until agency took future action); *see also Baur*, 352 F.3d at 640 (finding standing where risk was "not a future risk that awaits intervening events.")

Administrative decisions EPA has made and may make subsequent to promulgation of the Research Rule do not provide Petitioners with the standing they otherwise lack. Petitioners observe that EPA, following promulgation of the

Research Rule, has taken or proposed to take actions that raise pesticide exposure levels on certain pesticides. Pet. Resp. at 10-12.[1/]1 Petitioners further assert that this change is attributable to EPA's consideration of human studies. *Id.* Even assuming that this evidence is relevant to the standing inquiry,[1/]2 it simply confirms the existence of the numerous subsequent contingent steps that must be taken prior to any increased exposure that Petitioners rely upon for injury.

As explained in EPA's motion, the path from promulgation of the Research Rule to Petitioners' members' alleged increased exposure to pesticides requires that, as a result of the Research Rule: (1) a researcher has engaged in a study

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[1/] EPA disputes, among other things, Petitioners' characterization of EPA's recent actions to rely on certain human studies in making FIFRA and FFDCA findings, particularly their characterization of the studies relied upon. *See* Pet. Resp. at 10, 12 (alleging studies were "scientifically unsound" or "defective"). However, for purposes of this motion to dismiss, the Court need not address the merits of EPA's subsequent decisions establishing safety levels for pesticides.

[2/] The Court's jurisdiction, including the existence of standing, is to be assessed under the facts existing when the case is filed. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 569 n.4 (1992); *Hargrave v. Vermont*, 340 F.3d 27 (2d Cir. 2003). Subsequent actions cannot retroactively create injury (and hence jurisdiction) that did not exist at the outset. *Lujan*, 504 U.S. at 569 n.4. Although in *Baur*, the Court noted that "post-filing events may confirm that a plaintiff's fear of future harm is reasonable", *Baur*, 352 F.3d at 638 n. 11, in this case, the post-filing events only confirm that numerous contingent steps, including subsequent EPA decisions, must occur before any of Petitioners' members could potentially experience increased exposures to pesticides.

involving intentional human dosing of a pesticide that yields data that could support a higher safety level (*e.g.*, one that is arguably less stringent) for the pesticide; (2) EPA determines that the study was conducted ethically and was scientifically valid; (3) EPA relies upon the study in future action to establish a higher safety level under FFDCA or FIFRA; (4) such higher level would not be supported by other data considered by EPA during the rulemaking; and (5) one of Petitioners' members is then exposed to such higher level of pesticides.[1/]3 The declarations and documents submitted by Petitioners related to recent EPA actions regarding tolerance levels demonstrates that this multi-step path was followed in the post-Research Rule EPA actions cited by Petitioners. *See*, *e.g.*, Koh Declaration, Exhibits C - H.

In this case, as in *LEAN* and *Shoreham-Wading*, Petitioners' alleged injury will occur, if at all, only as a result of a number of agency actions independent of the Research Rule. When EPA sets tolerances or safety levels under FFDCA or

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[3/] In their response, Petitioners state that EPA does not deny that enhanced risk due to increased exposure can constitute an Article III injury. Pet. Resp. at 9. However, EPA does not agree that increased exposure itself will cause actual harm to any of Petitioners' members. When EPA determines the appropriate exposure level, based on all the relevant information before it, EPA determines a level that is safe under FFDCA and reasonably protective of human health and the environment under FIFRA.

FIFRA, and if that action adversely impacts Petitioners, Petitioners could seek to challenge that specific subsequent action. *See LEAN*, 87 F.3d at 1384. The outcome of such subsequent agency decisions does not give Petitioners standing to challenge the Research Rule.

3. Any Alleged Injury to Petitioners' Organizational Interests Is Insufficient to Provide Them With Standing to Challenge the Research Rule.

Petitioners also seek to establish organizational injury but, like their arguments on behalf of their members, they only identify injuries attributable to increased exposure to pesticides. Petitioners claim they will expend organization resources as a result of persons experiencing higher pesticide exposures. See Pet. Resp. at 15-17. However, for the reasons discussed in the prior section, the Research Rule itself does not result in the exposure of food consumers and farm workers to pesticides.[1/]4 Thus, Petitioners fail to establish organizational injury.

B. The Petitioners Cannot Satisfy the Causation Requirements of

[4/] Petitioners also note that Migrant Clinicians Network ("MCN") operates an Institutional Review Board, and claim that MCN is injured because the Research Rule places them in the "untenable position of implementing regulatory approval standards" with which they disagree. Pet. Resp. at 17 n. 9. The flaw in this argument is that the Research Rule does not limit an Institutional Review Board's discretion to disapprove or monitor studies using any more stringent standards it deems appropriate. *See* 40 C.F.R. §§ 26.403-26.1115, 26.1502-26.1507. Thus, the MCN's Institutional Review Board is not injured by the Research Rule.

Standing.

Petitioners identify no injury caused by the Research Rule. The Research Rule does not establish less stringent safety levels for pesticides. Further, the Research Rule contains no determination regarding the scientific validity and probative value of specific human research involving pesticides. The Research Rule does not require EPA to rely on any human studies.

Petitioners' argument attacks a causation theory not asserted by EPA. Pet. Resp. at 18. EPA does not contend that causation is missing "whenever an agency merely authorizes the action that causes an injury." *Id.* Rather, EPA contends that the Research Rule does not authorize any pesticide exposure that injures Petitioners' members. Because the Research Rule does not authorize pesticide exposures (other than to subjects of research), the pesticide exposures on which Petitioners base their injury are not caused by the Research Rule.

This causation theory is entirely consistent with *Baur v. Veneman*. The regulation reviewed in *Baur* authorized the use of downed livestock for human consumption notwithstanding Mr. Baur's claims of disease transmission. *Baur*, 352 F.3d at 637-38. Because the Court found that Mr. Baur's potential consumption of downed livestock constituted an injury-in-fact, it found the injury "arises directly from the USDA's regulatory policy of permitting the use of

downed cattle for human consumption. *Id.* at 640. No subsequent agency action was required to cause the injury. The *Baur* decision did not address a challenge to an agency action that does not authorize the exposures that Petitioners claim could cause them injury.

Petitioners are in no different position than the petitioners in *Shoreham-Wading*, who sought to challenge an agency ban on refueling a nuclear reactor by arguing that the ban laid the basis for future agency action that could pose environmental risks. Here, Petitioners claim the Research Rule lays the basis for future agency action that could increase their exposure to pesticides. That claim is insufficient to establish that their injury is fairly traceable to the Research Rule.[1/]5

CONCLUSION

For these reasons, the Court should dismiss the Petitioners' petitions for lack of jurisdiction.

Respectfully submitted,

SUE ELLEN WOOLDRIDGE

[5/] The Supreme Court's decision in *Bennett v. Spear*, 520 U.S. 154 (1997) is not apposite. In *Bennett*, the Court found standing to challenge a Fish and Wildlife Service biological opinion that was "virtually determinative of the subsequent Bureau of Reclamation decision." *Id.* at 170. In this case, the Research Rule makes no determinations regarding any safety levels for any pesticides.

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August 15, 2006

Angela Huskey/DC/USEPA/US	To	Brenda Mallory, Keith Matthews, Philip Ross
	cc	
11/25/2009 09:10 AM	bcc	
	Subject	Fw: NRDC v EPA (human research rule)

Attorney-Client Communication
Attorney Work Product
Pre-Decisional/Deliberative
Privileged and Confidential--Do Not Release

FYI...

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----- Forwarded by Angela Huskey/DC/USEPA/US on 11/25/2009 09:09 AM -----

From:	"Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ.GOV>
To:	"Wall, Michael" <mwall@nrdc.org>, "Jan Hasselman" <jhasselman@earthjustice.org>, <vruiz@farmworkerjustice.org>
Cc:	Angela Huskey/DC/USEPA/US@EPA
Date:	11/24/2009 07:05 PM
Subject:	NRDC v EPA (human research rule)

Counsel:

I have attached a red-lined and clean version of a revised draft settlement agreement. The red-lined document shows changes from EPA's proposed agreement (not from Petitioners' counterproposal). EPA would like to discuss the proposed agreement with you during the week of November 30. If possible, EPA proposes that we include counsel to the DDVP litigation in this call.

Please propose a couple times for a conference next week (not Monday).

Alan panna settlement agmt 11.24 clean.pdf panna settlement agmt 11.24 redline.pdf

SETTLEMENT AGREEMENT

This Settlement Agreement is entered into by and among Petitioners Natural Resources Defense Council, Inc., Pesticide Action Network North America, Pineros y Campesinos Unidos Del Noroeste, Physicians for Social Responsibility - San Francisco, Farm Labor Organizing Committee, AFL-CIO, and Migrant Clinicians Network (collectively "Petitioners") and the U.S. Environmental Protection Agency ("EPA").

WHEREAS, on February 6, 2006, EPA published in the Federal Register a final rule entitled "Protections for Subjects in Human Research." *See* 71 Fed. Reg. 6138 (Feb. 6, 2006) (the "2006 final rule");

WHEREAS, the Petitioners filed four petitions for review of the 2006 final rule, which were consolidated in the United States Court of Appeals for the Second Circuit, Case Nos. 06-0820-ag, 06-1895-ag, 06-2149-ag, 06-2360-ag (2nd Cir.);

WHEREAS, the Petitioners and EPA (collectively, "the Parties") briefed the case and presented oral argument before the court on January 17, 2008;

WHEREAS, the Parties wish to settle the Petitioners' petitions for review;

WHEREAS, settlement of the Petitioners' petitions is in the public interest;

NOW, THEREFORE, without admission of any issues of fact or law, or waiver of any claim or defense, either factual or legal, the Parties agree as follows:

Specific Provisions

1. EPA agrees to conduct notice-and-comment rulemaking in accordance with the Administrative Procedure Act on the issue of whether the 2006 final rule should be amended.

2. No later than seven months after this Settlement Agreement is filed with the court, EPA agrees to sign a notice of proposed rulemaking that proposes, at a minimum, the amendments to the 2006 final rule as substantially consistent with

Exhibit A. After considering any public comments received, EPA agrees to take final action on the proposed rule, which may include signing a notice of final rulemaking, no later than nineteen months after this settlement agreement is filed with the court.

3. If EPA amends any provisions of the 2006 final rule related to the standards for review or acceptance of human research initiated prior to April 7, 2006, EPA intends, within twelve months following publication of the notice of final rulemaking on the issue described in Paragraph 1, to do all of the following: (a) review each of the studies listed below and make an initial determination on whether it meets the applicable acceptance standards of any amendments to the 2006 final rule; and (b) schedule and hold a meeting with the Human Studies Review Board seeking its recommendations concerning the acceptability of these studies under the standards of any amendments to the 2006 final rule and the appropriateness of Agency reliance on these studies for the purpose or purposes proposed by EPA; and (c) determine, after considering the HSRB's final recommendations regarding the studies, whether those studies are acceptable for EPA to rely on under the standards of any amendments to the 2006 Final Rule. EPA intends to provide a copy of such determination to the petitioners. The studies within the scope of this paragraph are as follows:

For aldicarb:

Wyld, P.; Watson, C.; Nimmo, W.; et al. (1992) A Safety and Tolerability Study of Aldicarb at Various Dose Levels in Healthy Male and Female Volunteers: Lab Project No. 003237. Unpublished study prepared by Inveresk Clinical Research. 372 p. (MRID 42373001), as supplemented by

Cameron, A. (2003) Supplementary Report to: A Safety and Tolerability Study of Aldicarb at Various Dose Levels in Healthy Male and Female Volunteers: Final Report. Project Number: 003237, SOP/REC/030. Unpublished study prepared by Inveresk Research International and BCG (Europe) Ltd. 136 p. (MRID 46131001), and

Tobia, A. (2005) Bayer CropScience Response to EPA Request for Clarification Concerning the 1992 Wyld et al Aldicarb Study with Human Volunteers. Unpublished study prepared by Bayer CropScience, Research Triangle Park, NC, under Report No. BCS 003237-1. 40 p. with 19 p. confidential appendix. (MRID 46613001).

For amitraz:

Campbell, J. (1984) A Comparison of the metabolism of 14-C Amitraz in rat, mouse, baboon and human. Unpublished study performed by FBC Ltd., Chesterford Park Research Station, UK, under project number Metab/84/01. 20 p. MRID 00160964,

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Cass, L. (1992) T-344, Amitraz: Report of a Double Blind Tolerance Study of Amitraz in Six Adult Healthy Volunteers: Lab Project Number: RD 197/20170. Unpublished study prepared by Simbec Research Ltd. 136 p. MRID 43283101.

4. If EPA determines that any of the studies listed above for aldicarb or amitraz are not acceptable for EPA to rely on under the standards of any amendments to the 2006 final rule, EPA intends to incorporate those findings into its registration review of aldicarb or amitraz, as appropriate under FIFRA section 3(g).

5. With regard to dichlorvos (DDVP), EPA intends to take the actions as specified in the settlement agreement filed in *NRDC v. EPA*, in the United States Court of Appeals for the Second Circuit, Case No. 08-3771.

Procedural Matters

6. Upon execution of this Settlement Agreement by the Parties, the Petitioners and EPA agree to file a joint motion requesting that the court extend the stay in Case Nos. 06-0820-ag, 06-1895-ag, 06-2149-ag, 06-2360-ag (2nd Cir.), pending completion of the activities set forth in paragraphs 1 and 2. This Settlement Agreement shall be appended to that joint motion.

7. If EPA takes the actions described in paragraph 2, by the schedule contained in paragraph 2, then the Petitioners and EPA agree to file a joint motion in accordance with Rule 42 of the Federal Rules of Appellate Procedure for dismissal with prejudice of Case Nos. 06-0820-ag, 06-1895-ag, 06-2149-ag, 06-2360-ag (2nd Cir.).

Petitioners' Remedies

8. If EPA fails to take the actions described in paragraph 2, by the schedule contained in paragraph 2, then the Petitioners' sole remedy shall be the right to reactivate their petitions for review of the 2006 final rule and request that the Court proceed to issue a decision in the consolidated cases. The Petitioners agree to give EPA thirty days' notice prior to exercising their rights under this paragraph.

9. Any challenge to any amendments to the 2006 final rule must be brought in a new action.

General Provisions

10. Nothing in the terms of this Settlement Agreement shall be construed to limit or modify the discretion accorded EPA by the Department of the Interior, Environment and Related Agencies Appropriations Act, 2006; the Federal Food, Drug, and Cosmetic Act; the Federal Insecticide, Fungicide and Rodenticide Act; or general principles of administrative law.

11. Nothing in this Settlement Agreement shall be construed to limit or modify EPA's discretion to alter, amend, or revise 40 C.F.R. Parts 26 and 150 through 180, or to promulgate superseding rules or subsequent guidance. Nothing in this Settlement Agreement shall be construed to limit or modify EPA's discretion to propose additional regulatory changes in the same notice of proposed rulemaking signed pursuant to paragraph 2 and to finalize additional or different regulatory changes in the same notice of final rulemaking signed pursuant to paragraph 2.

12. Until any amendments to the Final Rule become effective, the Final Rule remains in effect.

13. This is the entire Settlement Agreement between the Parties with respect to the Petitioners' petitions for review of the 2006 final rule. All prior conversations, meetings, discussions, drafts, and writings of any kind are specifically superseded by this Settlement Agreement and may not be used by the Parties to vary or contest the terms of this Settlement Agreement, or as evidence of the Parties' intent in entering into this Settlement Agreement.

14. The Parties may agree in writing to modify any provision of this Settlement Agreement.

15. Nothing in this Settlement Agreement shall be construed to constitute an admission of any issue of fact, law, or liability by any of the Parties. Except as expressly provided in this Settlement Agreement, none of the Parties waives or relinquishes any legal rights, claims, or defenses it may have.

16. Petitioners reserve any right they may have to seek reasonable costs of litigation, including attorneys' fees, incurred in this litigation pursuant to 28 U.S.C. § 2412. EPA reserves its right to object to the award of any such costs and fees.

17. The undersigned representatives of each Party certify that they are fully authorized by the Party or Parties they represent to bind the respective Parties to the terms of this Settlement Agreement. This Settlement Agreement may be signed in counterparts, which, taken together, shall constitute the whole. This Settlement Agreement will be deemed to be executed and shall become effective when it has been signed by all of the representatives of the Parties set forth below.

18. No provision of this Settlement Agreement shall be interpreted as or constitute a commitment or requirement that EPA obligate or pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. § 1341, or take actions in contravention of the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706, or any other law or regulation, either substantive or procedural.

19. It is hereby expressly understood and agreed that this Settlement Agreement was jointly drafted by the Parties. Accordingly, the Parties hereby agree that any and all rules of construction to the effect that ambiguity is construed against the drafting party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Settlement Agreement.

20. Circumstances outside the reasonable control of EPA could possibly delay compliance with the schedule established in paragraphs 2 and 3. Such situations include, but are not limited to, a government shut-down such as occurred in 1995 and 1996, or catastrophic environmental events requiring immediate and/or time-consuming response by EPA. Should a delay occur due to such circumstances, any resulting failure to meet the timetables set forth herein shall not constitute a failure to comply with the terms of this Settlement Agreement, and any deadlines shall be extended one day for each day of the delay. EPA will provide the Petitioners with notice as soon as is reasonably possible under the circumstances in the event that EPA invokes this term of the Settlement Agreement and will provide Petitioners with an explanation of EPA's basis for invoking the provisions of this Paragraph. The provisions of this Paragraph shall not limit Petitioners' right to petition the Court to lift the stay issued pursuant to Paragraph 6, except that the court may take any delays described by this Paragraph into account in determining whether to lift the stay.

COUNSEL FOR PETITIONERS NATURAL RESOURCES DEFENSE COUNCIL, PHYSICIANS FOR SOCIAL RESPONSIBILITY - SAN FRANCISCO, FARM LABOR ORGANIZING COMMITTEE, AFL-CIO, AND MIGRANT CLINICIANS NETWORK:

Date: _____

_____

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COUNSEL FOR PETITIONERS PESTICIDE ACTION NETWORK NORTH AMERICA AND PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE

Date: _____

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(303) 844-1366

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2. No later than ~~ten~~ seven months after this Settlement Agreement is filed with the court, EPA ~~intends~~ agrees to sign a notice of proposed rulemaking that

proposes, at a minimum, the amendments to the 2006 final rule as substantially ~~contained in~~ consistent with Exhibit A. After considering any public comments received, EPA ~~intends~~ agrees to take final action on the proposed rule, which may include signing a notice of final rulemaking, no later than ~~fourteen months after the notice of proposed rulemaking is published in the Federal Register.~~ nineteen months after this settlement agreement is filed with the court.

3. If EPA amends any provisions of the 2006 final rule ~~impacting~~ related to the standards for review or acceptance of human research initiated prior to April 7, 2006, EPA intends, within twelve months following publication of the notice of final rulemaking on the issue described in Paragraph 1, to do ~~both~~ all of the following: (a) review each of the studies listed below and make an initial determination on whether it meets the applicable acceptance standards of any amendments to the 2006 final rule; and (b) schedule and hold a meeting with ~~solicit the recommendations of~~ the Human Studies Review Board seeking its recommendations concerning the acceptability of these studies under the standards of any amendments to the 2006 final rule and the appropriateness of Agency reliance on these studies for the purpose or purposes proposed by EPA; and (c) determine, after considering the HSRB's final recommendations regarding the studies, whether those studies are acceptable for EPA to rely on under the standards of any amendments to the 2006 Final Rule. EPA intends to provide a copy of such determination to the petitioners. The studies within the scope of this paragraph are as follows: -

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~~4. No later than three months after receiving the HSRB's final recommendations regarding the human studies listed above, EPA intends to determine whether those studies are acceptable for EPA to rely on under the standards of any amendments to the 2006 final rule.~~

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14. The Parties may agree in writing to modify any provision of this Settlement Agreement.

15. Nothing in this Settlement Agreement shall be construed to constitute an admission of any issue of fact, law, or liability by any of the Parties. Except as expressly provided in this Settlement Agreement, none of the Parties waives or relinquishes any legal rights, claims, or defenses it may have.

16. Petitioners reserve any right they may have to seek reasonable costs of litigation, including attorneys' fees, incurred in this litigation pursuant to 28 U.S.C. § 2412. EPA reserves its right to object to the award of any such costs and fees.

17. The undersigned representatives of each Party certify that they are fully authorized by the Party or Parties they represent to bind the respective Parties to the terms of this Settlement Agreement. This Settlement Agreement may be signed in counterparts, which, taken together, shall constitute the whole. This Settlement

Agreement will be deemed to be executed and shall become effective when it has been signed by all of the representatives of the Parties set forth below.

18. No provision of this Settlement Agreement shall be interpreted as or constitute a commitment or requirement that EPA obligate or pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. § 1341, or take actions in contravention of the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706, or any other law or regulation, either substantive or procedural.

19. It is hereby expressly understood and agreed that this Settlement Agreement was jointly drafted by the Parties. Accordingly, the Parties hereby agree that any and all rules of construction to the effect that ambiguity is construed against the drafting party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Settlement Agreement.

20. Circumstances outside the reasonable control of EPA could possibly delay compliance with the schedule established in paragraphs 2 and 3~~ through 6~~. Such situations include, but are not limited to, a government shut-down such as occurred in 1995 and 1996, or catastrophic environmental events requiring immediate and/or time-consuming response by EPA. Should a delay occur due to such circumstances, any resulting failure to meet the timetables set forth herein shall not constitute a failure to comply with the terms of this Settlement Agreement, and any deadlines shall be extended one day for each day of the delay. EPA will provide the Petitioners with notice as soon as is reasonably possible under the circumstances in the event that EPA

invokes this term of the Settlement Agreement and will provide Petitioners with an explanation of EPA's basis for invoking the provisions of this Paragraph. The provisions of this Paragraph shall not limit Petitioners' right to petition the Court to lift the stay issued pursuant to Paragraph ~~7~~6, except that the court may take any delays described by this Paragraph into account in determining whether to ~~the conditions for~~ lift~~ing~~ the stay ~~have been met~~.

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United States Court of Appeals
for the
Second Circuit

NATURAL RESOURCES DEFENSE COUNCIL, INC., PESTICIDE ACTION NETWORK NORTH AMERICA, PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE, PHYSICIANS FOR SOCIAL RESPONSIBILITY-SAN FRANCISCO, FARM LABOR ORGANIZING COMMITTEE, AFL-CIO, and MIGRANT CLINICIANS NETWORK,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

ON PETITION FOR REVIEW OF AN ORDER OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BRIEF OF AMICI CURIAE SENATOR BARBARA BOXER, SENATOR BILL NELSON, CONGRESSMAN HENRY A. WAXMAN, and CONGRESSWOMAN HILDA SOLIS IN SUPPORT OF PETITIONERS

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INTEREST OF THE AMICUS CURIAE

Amici Senator Barbara Boxer, Senator Bill Nelson, Congressman Henry A. Waxman, and Congresswoman Hilda Solis urge the United States Court of Appeals for the Second Circuit to rule in favor of petitioners. This case turns on whether the EPA's Human Testing Rule, 71 Fed. Reg. 6138-01 (Feb. 6, 2006), encoded at 40 C.F.R. Parts 9 and 26, is inconsistent with the mandate provided by Congress in the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, § 201, Pub. L. 109-54, 119 Stat. 499. Amici were sponsors, co-sponsors, or supporters of the relevant provisions in the Senate and House of Representatives, and have an interest in ensuring that EPA observes both the letter of the statute and its intent.

ARGUMENT

Congress passed a law requiring EPA to promulgate its human testing rule because of the realization that without government controls, humans could be dosed with pesticides without their consent in an effort to weaken safety standards for those pesticides - or at least their consent in any real, freely given sense. Congress was concerned about the potential for human subjects to be injured through their participation in pesticide studies. Congress was particularly concerned about pregnant women, infants, and

children being induced into participating as human guinea pigs. Not only are these subpopulations potentially more sensitive to the effects of pesticides, but pesticide registrants may have a natural desire to conduct research on these subpopulations given that actual data could result in significantly more lenient regulatory standards.

Because EPA's rule fails to prevent this sort of testing, despite Congress's clear instructions to the contrary, we file this amicus brief in support of petitioners. Because EPA's rule is inconsistent with Congress's statutory guidance and the very purpose of Congress's decision to legislate, it must be vacated and remanded.

I. EPA Failed To Follow Congress's Clear Intent To Prohibit Pesticide Testing On Pregnant Women And Children.

The plain language of the statute establishes that Congress wanted pesticide testing on pregnant women, infants, and children banned. Congress directed EPA to prohibit "the use of pregnant women, infants, or children as subjects." § 201. The conference report indicated that "[c]oncern is particularly acute for pregnant women, fetuses, and children." H. Rep. No. 109-188 (2005). Congress acted because, as co-sponsor Rep. Hilda Solis noted, "[i]ntentional human toxicity testing has a troubling history that includes manipulation and abuse of the most vulnerable members of society." 151 Cong. Rec. H7018, 7021 (daily ed. July 28, 2005).

Accordingly, as Senator Barbara Boxer explained**,** a comprehensive regulatory scheme was crucial if "one cares about protecting children and families." 151 Cong. Rec. S7552, 7554 (daily ed. June 29, 2005) (statement of Sen. Boxer).

EPA's rule fails to implement the ban required by Congress. Instead, the rule only prohibits the use of data collected from pesticide experimentation on pregnant women, infants, and children for certain purposes. *See* 40 C.F.R. §§ 26.1701, 26.1702, & 26.1706 (2006).

Specifically, Congress did not limit its instructions to EPA to cover actions pursuant to only two of the many statutes that the agency administers. The statute says that "[s]uch rule shall not permit the use of pregnant women, infants or children as subjects." § 201. The EPA regulation, in contrast, only provides that its regulations "appl[y] to EPA's decisions whether to rely on its actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. § 136 et seq.) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 346a)." Since EPA's regulation fails by its own terms to apply the ban to its other programs for which human testing may be permissible – and EPA might consider such studies pursuant to its regulatory authority under the Safe Drinking Water Act and the Clean Water Act, for example – it is inconsistent with that

instruction. *See Yellow Transp., Inc. v. Michigan*, 537 U.S. 36, 45 (2002) ("If the statute speaks clearly to the precise question at issue, Congress must give effect to the unambiguously expressed intent of Congress.") (internal quotation marks omitted); *see also Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-843 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

Congress did not, in short, limit its statutory instructions to FIFRA and the FDCA. But because EPA interpreted its instructions as limited to those two regulatory programs, its rule violates the plain meaning of Section 201.

Congress legislated comprehensively because EPA itself has an inconsistent record on the protection of pregnant women, infants and children from the harms of human testing. The agency planned a joint federal-industry study to test the effect of chemicals on Florida children from newborn to three years old as part of the Children's Environmental Exposure Research Study (CHEERS). Michael Janofsky, *Nominee Challenged Over Program on Pesticides*, New York Times, Apr. 7, 2005**,** at A19. In exchange for participation in these tests, EPA planned to offer participating families $970, a free video camera, a T-shirt, and a framed

certificate of appreciation. David DeCamp, *EPA Drops Contested Pesticide Study*, Florida Times, April 9, 2005.

Congress found EPA's conduct deeply troubling. Florida senator Bill Nelson declared that he had had a "bellyful of this kind of stuff to come in on the citizens of the State of Florida, and I want it stopped." 151 Cong. Rec. S7554, 7554 (daily ed. June 29, 2005) (statement of Sen. Nelson). Congressman Sanford Bishop characterized CHEERS as "a trifecta of unethical, immoral, and unscientific research," 151 Cong. Rec. H3651, 3670 (daily ed. May 19, 2005) (statement of Rep. Bishop), and many others agreed.[1] Congress's concerns are, of course, well-grounded in established science, as well as ethics. More than a decade before EPA developed the CHEERS program, the National Academy of Sciences raised concerns that exposure of children to pesticides like that involved in the CHEERS study may cause "acute organophosphate pesticide poisoning." *See* U.S. House of Representatives, Committee on Government Reform—Minority Staff Special Investigations Division and United States Senate, Office of Senator Barbara Boxer, Environmental Staff, *Human Pesticide Experiments*, at 10

[1] *See also* 151 Cong. Rec. H7018, 7021 (July 28, 2005) (statement of Rep. Solis) (noting that "the Solis-Bishop amendment is supported by environmental and diverse religious organizations and among more than 80,000 others who have written to me saying they oppose the CHEERS study and support a moratorium on this type of testing.")

(June 2005), available at http://www.democrats.reform.house.gov/Documents/20050627115401-68567.pdf. (last visited Oct. 2, 2006) (A678[2]) [hereinafter *Human Pesticide Experiments*].

The CHEERS study provided unethical incentives and misleading disclosures and was much more than simply an observational study. Through the study, EPA directly encouraged and endorsed the exposure of very young children to toxic pesticides, placing them in harm's way and changing the status quo.

Congress accordingly tried to make sure that its intention to ban testing on pregnant women, infants, and children was very clear. The floor statements of the sponsors and supporters of the bill reaffirm the intent that EPA's implementation ignores. "A [floor] statement of one of the legislation's sponsors ... deserves to be accorded substantial weight in interpreting the statute." *Federal Energy Administration v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976); *see also American Trucking Ass'n, Inc. v. ICC*, 697 F.2d 1146, 1149 (D.C. Cir. 1983) (Scalia, J.) (relying on floor statements as part of the relevant legislative history of a statute); *Southeast*

[2] Citations to 'A___' are to the Appendix filed by Petitioners with their Opening Brief.

Shipyard Ass'n v. United States, 979 F.2d 1541, 1546 (D.C. Cir. 1992) (relying on floor debate to establish legislative intent).

Senator Bill Nelson observed that "[a]ny exposure of an infant child or a pregnant woman to a toxin basically should be prohibited, even in doses that are not expected to do any harm." 151 Cong. Rec. S7552, 7554 (daily ed. June 29, 2005) (statement of Sen. Nelson). He did so because, as he explained, "[t]he human testing of pesticides offers no therapeutic benefit." *Id.* Congressman Alcee Hastings noted that the legislation Congress passed "stops EPA from intentionally exposing pregnant women and children to pesticides." 151 Cong. Rec. H6941, 6942 (daily ed. July 28, 2005) (statement of Rep. Hastings)**.**

EPA's failure to follow Congress's clear instructions, given in both the language of the statute and floor debates, prohibiting pesticide testing on pregnant women, infants, and children is sufficient reason to vacate and remand the rule to the agency.

II. Congress Intended Consistency Between the Rule and the Seventeen Principles Set Forth in the 2004 National Academy of Sciences Report, Not the More General "Belmont Principles."

Section 201 was Congress's attempt to set minimum ethical and scientific requirements for EPA's human testing rule. Congress recognized that in absence of guidelines, EPA had been reviewing "over 20 human

dosing studies . . . [that] routinely violate ethical and scientific standards laid out in the Nuremburg Code, the Declaration of Helsinki, the 'Common Rule,' and the National Academy of Sciences recommendations on human testing." *See* 151 Cong. Rec. S7553 (daily ed. June 29, 2005) (statement of Sen. Boxer) (describing statements made prior to Conference supporting two competing amendments considered by the Senate, one also applying to "third-party intentional human dosing studies for pesticides"). Accordingly, Congress sought to constrain the EPA's discretion by putting something "in place that would guide these experiments" and EPA's use and consideration of them. *See id.*

Congress incorporated the principles of the 2004 NAS report into the protections it wanted EPA to provide test subjects. In fact, it said in Section 201 that the EPA rule "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences." The only exceptions to strict compliance with that report would be for occasions where the express language of section 201 provided for other, independent protections, such as the ban on the use of pregnant women, infants, and children as test subjects. This report contained seventeen concrete "recommendations to strengthen oversight and provide guidance for the use of intentional human dosing studies," A129, which were developed in response to similar concerns as

those before us now, A125-27. These recommendations ranged from issuing guidelines for determining whether intentional human dosing is scientifically valid, A130, to developing best practices for informed consent, A135-36. Moreover, these recommendations were purposefully specific, not general. *See* A129 ("Because of the complexity of the issues considered by the committee and the need to be specific about the proposals being made, the recommendations follow.").

But the EPA failed to comply with the legislative mandate to follow the seventeen recommendations of the 2004 NAS Report. Instead, the EPA relied on "'fundamental ethical principles' identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) in its report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the 'Belmont Report')." 71 Fed. Reg. 6138, 6164. In other words, according to the EPA, "principles proposed in the 2004 report of the National Academy of Sciences" refers not to the 2004 NAS Report itself, but to a report mentioned only 12 times within the 208 pages of the 2004 NAS Report. *See* A108-331, *available at* http://darwin.nap.edu/ books/0309091721/html/ (2004) (using search term "Belmont"). Such a conclusion contravenes the plain language of Congress, which nowhere mentioned the report EPA used,

and is unsupported by either traditional statutory analysis or the legislative history. *Chevron U.S.A., Inc.*, 467 U.S. at 842-43 (examining "whether Congress has directly spoken to the precise question at issue" to determine whether to uphold an agency's interpretation of a statute); *see also id.* at 843 n.9 (applying traditional tools of statutory construction). Indeed, aside from conflicting with Congress's clear intent, EPA's sole reliance on the Belmont Report is beyond the scope permitted by Congress. *See id.* at 843-44 (allowing a rule to stand only if it is based on a permissible construction of the authorizing statute). Accordingly, this Court should set aside the human testing rule.

A. Traditional Principles Of Statutory Interpretation Demonstrate That Congress Intended Consistency With The Seventeen Recommendations 2004 NAS Report.

In requiring EPA to rely upon the "principles proposed in the 2004 report of the National Academy of Sciences," § 201, Congress intended EPA to base its rule on the seventeen enumerated scientific and ethical recommendations of the NAS Report. It had no intention of allowing the vague language of the Belmont Report to supersede the seventeen concrete recommendations of the NAS Report. While the Belmont Report is referenced in the 2004 NAS Report, neither the Belmont Report nor any principles contained in it are "proposed" in the NAS Report in the sense that

the NAS offered them as "suggestions" or "offerings." *Random House Unabridged Dictionary* 1551 (2d ed. 1993) (defining "propose" as "to offer or suggest (a matter, subject, case, etc.) for consideration, acceptance, or action"). Instead, any principles contained in the Belmont Report were proposed in 1979 by the National Commission. A1286-87; A172-73 (identifying as "basic ethical principles" the concepts of "respect for persons," "beneficence," and "justice" as being put forth by the National Commission).

Indeed, the NAS recognized that it was not "proposing" any of the principles contained in the Belmont Report, in contrast to its seventeen "proposals," which did reflect its "own judgments." A235. The NAS consistently describes the Belmont Report as containing a separate set of principles apart from NAS's own,[3] even though the NAS recognized that the NAS Report may "draw[] on," A234, both the Belmont Report and other

[3] EPA's attempt to characterize the NAS as "mak[ing] the point clearly that they did not propose new principles," 71 Fed. Reg. 6138, 6164, is misleading. Although the NAS did acknowledge that it "was not required to invent the basic *standards* that govern human research in the United States," A127, 156 (emphasis added), the NAS Report focused on determining "how those standards should be applied in the particular case of intentional human dosing studies conducted by third parties for EPA regulatory purposes." A128. In doing so, the NAS recognized "the need to be specific," and thus set forth a series of seventeen new "recommendations to strengthen oversight and provide guidance for the use of intentional human dosing studies at EPA." A129.

"authoritative statements of principle," A127. For example, the NAS Report describes the Belmont Report as the creation of the National Commission. *See* A172 ("The National Commission is perhaps best known for its Belmont Report"). Similarly, the NAS treats the principles of "respect for persons, beneficence and justice" as not its *own* principles, but those contained in the Belmont Report. *See, e.g.*, A173 ("The Belmont Report recommended that additional attention be given to the equitable selection of participants.").

Bare reliance on "respect for persons," "beneficence," and "justice"—without the recommended specificity provided by the NAS Report—must also be rejected as inconsistent with Congress's mandate. Congress stated that the EPA's rule should be "consistent with the principles proposed" in the 2004 NAS Report. § 201. The 2004 NAS Report, in turn, rejected complete reliance on earlier sources of principles, such as the Belmont Report, because they were "frequently unclear, indeterminate, inconsistent, and even contradictory" in terms of providing sufficient guidance to EPA. A235. Thus the NAS proposed its own set of recommendations—recommendations that covered both "scientific and ethical principles"—and even recommended a procedural framework for their implementation. A168. These recommendations are what Congress meant EPA to rely upon, not the "general prescriptive judgments" in the Belmont Report.

Moreover, the "general prescriptive judgments" of the Belmont Report, A1288, cannot reasonably be conflated with the seventeen concrete recommendations—such as developing and disseminating to Institutional Review Boards, investigators, and sponsors a list of best practices for informed consent, A245, and operating on the "strong presumption that data obtained *after* implementation of the new rules that do not meet the ethical standards described in this report will not be considered," A250 (emphasis in original)—of the NAS Report. *See Sierra Club v. EPA*, 356 F.3d 296, 306 (D.C. Cir. 2004) (recognizing that an agency cannot take an action that abandoned or supplanted the model upon which Congress mandated the action be "based"). The Belmont Report provides "ethical" principles, rather than the scientific and ethical principles of the NAS Report. A1288-89.

This plain-language interpretation of Congress's mandate as requiring EPA to rely upon the seventeen recommendations in the NAS Report is further supported by the interpretive canon of deriving the meaning of a word "from the company it keeps." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995). Here, Congress specifically listed two sets of "principles" with which EPA's rule must be consistent: the 2004 NAS Report, and the "Nuremberg Code with respect to human experimentation." § 201. The

Nuremburg Code, much like the 2004 NAS Report, contains ten standards providing specific directives to guide human experiments: from emphasizing the absolute essentiality of voluntary consent," A529, to allowing the conduct of human experiments only if the studies provide results "unprocurable by other methods or means of study," *id.*, to avoiding "all unnecessary physical and mental suffering and injury." *Id.* The structural similarity of the ten principles of the Nuremberg Code with the seventeen principles in the 2004 NAS Report (and the structural dissimilarity of the principles in the Nuremburg Code with the three general concepts of the Belmont Report) further establishes Congress's intent that EPA rely on the actual principles set forth by the NAS Report, not the NAS's report minimal reference to the Belmont Report. Otherwise, "principles" would be ascribed a meaning "so broad that it is inconsistent with its accompanying words, thus giving 'unintended breadth to the Acts of Congress.'" *Gustafson*, 513 U.S. at 575 (citing *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961)).

B. The Legislative History Also Supports The Use Of The Seventeen Recommendations In The 2004 NAS Report.

The legislative history behind the Congressional mandate further establishes its intent that EPA rely on the seventeen standards set forth by the NAS in its 2004 Report, rather those described by the National Committee in its Belmont Report. *See Chevron*, 467 U.S. at 843 n.9 (urging

reliance on "traditional tools of statutory interpretation," including legislative history); *see Babbitt v. Sweet Home Chapter of Cmty for a Great Or*, 515 U.S. 687, 704-08 (1995) (examining Senate and House Reports to hold that Congress intended the challenged "take" provision "to apply broadly to cover indirect as well as purposeful actions"). The discussions in the House debate regarding the Conference Report to which Section 201 was attached on July 28, 2005, not only consistently refer to the 2004 NAS Report and fail to refer to the Belmont Report, but also require compliance with "stringent criteria," which is lacking in the Belmont Report. 151 Cong. Rec. H7019 (daily ed. July 28, 2005).

As Representative Norman Dicks stated in his introduction to the Conference Report, both the House and the Senate, in the conference report, wanted EPA to stop the use of humans during pesticide testing "until EPA develops regulations reflecting the recommendation of the National Academy of Science [sic] and follows the Nuremburg protocols." 151 Cong. Rec. at H7019; *see also* 151 Cong. Rec. at H7021 (Rep. Solis) (criticizing EPA's earlier proposed rule as "contrary to the recommendations of the NAS and the ethical guidelines of the Nuremburg Code that we require in this amendment"). This language tracks the language used in the 2004 NAS Report for its seventeen principles—that is, "recommendations,"

A129. This language also demonstrates that Congress wanted EPA to follow those proposals actually put forth by the NAS, rather than simply those that might have been referred to by the NAS in its 2004 Report.

III. The EPA Rule Is Inconsistent With The Nuremberg Code That Congress Adopted By Statute.

Congress required EPA to act consistently with the Nuremberg Code because that code reflects the importance of obtaining meaningful consent before any tests can be conducted on humans for non-therapeutic purposes. The Nuremberg Code was devised by American and foreign prosecutors in the aftermath of World War II in the face of the terrible extremes to which human experimentation had been taken in Germany at that time. It is a document grounded in fundamental principles of human rights, adopted by countries around the world and agencies within the United States as the appropriate basis for the responsible and respectful use of human subjects for the purposes of scientific experimentation.

And Congress has made it the law for EPA to follow in this case. Congress required EPA to promulgate "strict scientific and ethical requirements that are consistent with . . . the principles of the Nuremberg Code," to ensure scientific rigor and to prevent ethical abuses in intentional human dosing toxicity studies for pesticides. *See* § 201.

EPA failed to follow Congress's instruction. The first principle articulated in the Nuremberg Code states:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. . . .

A529.

The EPA's rule does not conform to the Nuremberg principle of voluntary consent because the EPA rule violates the standards of 1) individualized personal consent 2) informed consent and 3) voluntary consent.

Nor is this new. Senator Boxer noted that studies had in the past "routinely violate[d] ethical and scientific standards laid out in the Nuremberg Code." 151 Cong. Rec. at S7553 (statement of Sen. Boxer).

These violations prompted Congressional action. Congress' goal was to stop EPA from relying on studies that lacked fundamentally fair consent. As Representative Solis explained, Section 201 was designed to ensure that "EPA may not consider or rely on any intentional human-dosing study that does not meet the minimum ethical and scientific criteria recommended by

the Nuremberg Code."[4] 151 Cong. Rec. H7021, 7021 (daily ed. July 28, 2005) (statement of Rep. Solis).

Under the EPA rule, any "legally authorized representative" may give consent. 40 C.F.R. §§ 26.1116, 26.1117(a), (b)(1) & (b)(2). As defined by the EPA, a "legally authorized representative" is an "individual or judicial or other body authorized under applicable law to consent on the behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." 40 C.F.R. § 26.1102(c). By defining "legally authorized representative" under "applicable law," the meaning of "consent" varies depending on the site of experimentation – including sites in foreign countries that have not accepted American concepts of individual rights or the necessity of individual consent. Congress did not provide for consent by a representative and the Nuremberg Code expressly requires "[t]he voluntary consent of the human subject." EPA's rule violates the standard of

[4] As we observed in Part I of this brief, *supra*, sponsor statements "greatly aid in making the [statute's] purpose apparent." Max Radin, *A Short Way With Statutes*, 56 Harv. L. Rev. 388, 411 (1942); *see also Pub. Employees Ret. Sys. v. Betts*, 492 U.S. 158, 179 (1989) (giving weight to Senator Yarborough's views on the construction of the Age Discrimination in Employment Act because he was a sponsor); *Pacific Gas & Elec. Co. v. Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 220 n.23 (1983) (relying on a 1965 explanation by "an important figure in the drafting of the 1954 [Atomic Energy] Act"); *see, e.g., National Endowment for the Arts v. Finley*, 524 U.S. 569, 573-74 (1998) (sponsors' statements); *Conroy v. Aniskoff*, 507 U.S. 511, 516-17 & n. 12 (1993) (sponsors' statements).

individualized consent because it expressly allows "consent" to be given by an entity other than the human subject.

EPA's rule also fails to ensure that the human subject is appropriately informed of the risks presented by the research. The Nuremberg Code similarly explains, "before the acceptance of an affirmative decision by the experimental subject there should be made known to him … all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment." Contrarily, the EPA rule adopts old practices that have led to widespread misunderstanding about research risks among the subjects of that research. *See Human Pesticide Experiments* at 35-38 (finding that prior pesticide experiments on humans used such complex language in their consent forms that it is unlikely the volunteers understood the risks) (A703-05). The EPA's rule disseminates a pre-existing standard that has led to common violations of the Nuremberg Code's informed consent requirements.

EPA's rule similarly fails to ensure that human subjects who provide consent do so voluntarily. The Nuremberg Code demands that the human subject be "so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching,

or other ulterior form of constraint or coercion." Instead of adopting the Nuremberg's clear and absolute standard, EPA's rule provides for human studies to include undefined "additional safeguards" to protect "the rights and welfare" of subjects who "are likely to be vulnerable to coercion or undue influence." 40 C.F.R. § 26.1111. The indefinite standards allow total discretion to the conductors of the experiment.

There are significant deficiencies in the informed consent of the subjects tested in several of the experiments on which EPA has in the past relied, including the inadequate disclosure of potential harms, complex language, easily misunderstood consent forms, and plainly not obtaining consent.

Some experiments featured consent forms and accompanying information sheets that failed to explain or downplayed the health risks associated with the pesticide exposures involved in the experiments. *See Human Pesticide Experiments* at 35-38 (stating that the potential harms were not adequately disclosed Chloropicrin, Dimethoate, Amitraz (1998) and Amitraz (1992) studies) (A 703-05).

For example, consent forms in experiments involving dimethoate did not explain the relevant risks. The Dimethoate Experiment (2004), an organophosphate pesticide manufactured by BASF, utilized a consent form

that does not identify the test substance as a pesticide or describe potential health effects. *Human Pesticide Experiments* at 18 (A 686). Dimethoate had been identified by EPA as a suspected carcinogen, a developmental toxicant, and a neurotoxicant. Scorecard: the Pollution Information Site, *Chemical Profile: Dimethoate,* http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=60%2d51%2d5 (last visited Sept. 30, 2006). It is a suspected cardiovascular or blood toxicant, gastrointestinal or liver toxicant, kidney toxicant, and skin or sense organ toxicant. *Id*. The informed consent form used in the Dimethoate experiment did not identify any of these potential risks. *Human Pesticide Experiments* at 18 *(citing* W.J.A. Meuling and L. Roza, *Urinary Excretion Profile of Dimethoate and its Metabolites after Single Oral Administration of Dimethoate in Male Volunteers* (Dec. 28, 2004)) (A 686). Furthermore, the written information presented to test subjects states that "not a single health effect is expected" and characterizes the chemical as "used to protect or cure all kinds of plants, fruits and crops from disease." *Id.*

Even when risks are explained in the consent forms, the language is often so complex that participants do not understand the risks. *See Human Pesticide Experiments* at 35-38 (observing that three prior experiments used such complex language in their consent forms that it was unlikely the

volunteers understood to the risks) (A703-05). In a 1999 Phosmet study, an ethics committee identified "volunteer information [that] is difficult to understand," and recommended that "[s]ome effort should be made to simplify the volunteer information," although researchers declined to make any of these changes. *Id.* at 30 (quoting S. Freestone, S.J. Mair, & P. McFarlane, *A Randomised, Double Blind, Ascending Single Oral Dose Study with Phosmet to Determine the No Effect Level on Plasma and RBC Cholinesterase Activity* (June 4, 1999)) (A698).

Other studies have not even been able to establish that they ever obtained any kind of consent at all. A 1969 Dichlorvos experiment made no assertion of having obtained any informed consent, and congressional investigators were unable to obtain any evidence of consent from the principals behind 1997 Dichlorvos, 1996 Methyl Isothiocyanate, 1977 Ethephen, 1972 Ethrel, and 1971 Carbamates experiments. *Human Pesticide Experiments* at 35-38 (A703-05).

And of course, some terribly tragic cases of uninformed consent are not unknown to the federal government.[5] Nor are they unknown elsewhere.

[5] Consider the uninformed consent provided by the victims of the Tuskegee Syphilis Study, 400 of whom were permitted to suffer from the disease although the United States Public Health Service had a cure readily available for them. Experimenters continued this study even though a proven and 100% effective cure for syphilis had already been found. Barbara A. Noah,

EPA has documented troubling examples of English test subjects being dosed with the pesticide "Doom"[6] and Scottish subjects with orange juice laced with the insecticide Aldicarb.[7]

This rather sordid history of pesticide testing is particularly troubling because the Nuremberg Code has a long and distinguished history of

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The Participation of Underrepresented Minorities in Clinical Research, 29 Am. J. L. and Med. 221, 230 (2003) (describing how the Tuskegee studies continued some two decades after a cure for syphilis had become available). In some cases, researchers intervened to prevent treatment when other physicians diagnosed subjects as having syphilis. Predictably, many subjects died of syphilis during the study. *See generally Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study (*Susan M Reverby ed. 2000); Robert M. White, *Unraveling the Tuskegee Study of Untreated Syphilis,* 160 Archives of Internal Med. 585 (2000); Department of Health and Human Services: Center of Disease Control and Prevention, *The Tuskegee Timeline*, http://www.cdc.gov/nchstp/od/tuskegee/time.htm (last visited Sept. 28, 2006).

[6] *See* Molly Evans, *The English Patients: Human Experiments and Pesticide Policy*, The Environmental Working Group, July 1998, http://www.epa.gov/oscpmont/sap/meetings/1998/december/english.pdf (last visited Oct. 7, 2006) ("In three related studies conducted just last year for Amvac Chemical Corporation, headquartered in City of Commerce, California, for example, researchers at the Medeval Laboratories in Manchester, England dissolved a neurotoxic insecticide, dichlorvos, in corn oil and paid a small number of adult men to eat it in a test of the chemical's acute effects."). Dichlorvos is often marketed under the name "Doom." *Id.*

[7] *See id.* (documenting study commissioned by Rhone-Poulenc and conducted in 1992 on 38 men and 9 women at the Inveresk Clinical Laboratory in Scotland, "subjects were given a light breakfast on the day of the study, including a drink of orange juice" containing a placebo or various doses of aldicarb, an extremely toxic insecticide resulting in subject reports of "profuse sweating," "headaches," and "light-headedness").

protecting human subjects, as courts, agencies, and the international community have recognized.

The former have recognized that the code "is absolutely essential...to satisfy moral, ethical and legal concepts." *Washington v. Harper*, 494 U.S. 210, 238 (1990) (Steven, J., dissenting). The United States Military Tribunal that established the Nuremberg Code set a standard against which to judge German scientists who experimented with human subjects during the Holocaust. *See United States v. Stanley*, 483 U.S. 669, 687 (1987) (noting that the Nuremberg Code was created as uniform standard to govern scientists of permissible medical experiments in the Nuremberg Trials).[8] The code stands for the principle that "experimentation with unknowing

[8] The Nuremberg Code is the "most complete and authoritative statement of the law of informed consent to human experimentation." *Grimes v. Kennedy Krieger Institute, Inc*., 782 A.2d 807,835 (Md. 2001); *see also Whitlock v. Duke University* 637 F.Supp. 1463, 1470 (M.D.N.C.1986) (Nuremberg Code was adopted "as a proper statement of the law of informed consent in connection with the trials of German Scientists for human experimentation after World War II"); *Kaimowitz v. Michigan Dep't Mental Health*, No. 73 Civ. 19434-AW (Mich. Cir. Ct., Wayne County, July 10, 1973) (unreported), reprinted in A. Brooks, *Law, Psychiatry And The Mental Health System* 902 (1974) ("In the Nuremberg Judgment, the elements of what must guide us in decision are found. The involuntarily detained mental patient must have legal capacity to give consent. He must be so situated as to be able to exercise free power of choice without any element of force, fraud, deceit, duress, overreaching, or other ulterior form of restraint or coercion. He must have sufficient knowledge and comprehension of the subject matter to enable him to make an understanding decision. The decision must be a totally voluntary one on his part.").

human subjects is morally and legally unacceptable." *Id*. It "requires that the informed, voluntary, competent, and understanding consent of the research subject be obtained." *Grimes v. Kennedy Krieger Inst , Inc.*, 782 A.2d 807,835 (Md. 2001).

But EPA's rule fails to adhere to the code. Although, for example, the Code requires free choice by testing subjects "without the intervention of any element" of, among other things, "over-reaching, or other ulterior forms of constraint or coercion," A529, EPA's rule only requires that coercion be "minimized." The Nuremberg Code, and Congress's statute, is much more comprehensive.

Each and every principle of the Nuremberg Code, in short, has to be incorporated in the EPA rule in full, and the agency has failed to do so in the rule it has promulgated.

CONCLUSION

For the foregoing reasons amici members of Congress urge the court to vacate and remand the Human Testing Rule, 71 Fed. Reg. 6138-01 (Feb. 6, 2006), encoded at 40 C.F.R. Parts 9 and 26, to the agency for reconsideration.

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October 11, 2006

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This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 5,581 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2003 in a 14 point, Times New Roman font.

October 11, 2006

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Stanley N. Alpert

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Subject Fw: NRDC v EPA (Human Testing) - Petitioners' Reply Brief

FYI....Here is a copy of NRDC's reply brief for the human studies litigation.

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Subject NRDC v EPA (Human Testing) - Petitioners' Reply Brief

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Attached is Petitioners' Reply Brief. Hard copies, along with Petitioners' standing declarations, have been sent to Alan by Federal Express.

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In the U.S. Court of Appeals for the Second Circuit

Natural Resources Defense Council, Inc., Pesticide Action Network North America, Pineros y Campesinos Unidos Del Noroeste, Physicians for Social Responsibility-San Francisco, Farm Labor Organizing Committee, AFL-CIO, and Migrant Clinicians Network,
Petitioners,
v.

United States Environmental Protection Agency,
Respondent.

On Petition for Review of an Order of the
United States Environmental Protection Agency

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INTRODUCTION

The challenged Human Testing Rule has harmed and will continue to harm Petitioners and their members. The substantial and entirely uncontroverted evidence before this Court belies EPA's factual assertions to the contrary, and this Circuit and the Supreme Court have both rejected EPA's core Article III legal theory. The Court has jurisdiction and should proceed to the merits.

EPA's Human Testing Rule violates Section 201 because it allows intentional pesticide toxicity experiments on pregnant women and children in some circumstances, contravenes the principles proposed by the National Academy's 2004 Report, and is inconsistent with the Nuremberg Code. EPA ignores the statute's clear text in favor of an allegedly narrow legislative "policy," but disregards the stated policy of Section 201's enactors. EPA argues that most of the Nuremberg Code is precatory, although text and history show otherwise. EPA treats the National Academy's proposals as distractions, and disregards the evidence and canons of construction that disprove that treatment.

In short, EPA asks this Court to rewrite the law. The invitation should be rejected.

ARGUMENT

I. Petitioners Have Standing

The Human Testing Rule has caused EPA to raise exposure limits for pesticides to which Petitioners' members are exposed. A judicial order vacating the Rule would remove the cause of this injury. Petitioners' uncontroverted evidence establishes these facts and each element of Article III standing.

A. The Human Testing Rule Injures Petitioners and Their Members

Exposure to a toxic chemical is a well-recognized Article III injury. *See, e.g.*, *Friends of the Earth, Inc. v. Laidlaw*, 528 U.S. 167, 184-85 (2000); *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002). Indeed, this Court has held that even "health-related uncertainty," *see New York Public Interest Research Group v. Whitman*, 321 F.3d 316, 325, 326 (2d Cir. 2003) ("*NYPIRG*"), or an "increased risk" of exposure to a dangerous substance, *Baur v. Veneman*, 352 F.3d 625, 633 (2d Cir. 2003); *see also id.* at 627-28, 633-35, 641-42, are constitutionally cognizable.[1]

[1] This Court's recognition that increased risk of harm is a cognizable injury comports both with common experience (e.g., people pay for insurance against risks of future injury) and with the law of other Circuits. *See Central Delta Water Agency v. United States*, 306 F.3d 938, 947-948 (9th Cir. 2002); *Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001); *Johnson v. Allsteel, Inc.*, 259 F.3d 885, 888 (7th Cir. 2001); *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 160 (4th Cir. 2000); *Louisiana Envtl. Action Network v. EPA*, 172 F.3d 65, 67-68 (D.C. Cir. 1999); *Walters v. Edgar*, 163 F.3d 430, 434 (7th Cir. 1998), *cert.*

The uncontroverted evidence proves precisely such injuries here. Petitioners' members include farmworkers who apply and are exposed to pesticides in the fields where they work; families who live downwind of agricultural spray; and consumers who eat and drink pesticide-contaminated food and water in their normal diet. *See* D8-9, D84-88, D89-90, D91, D92, D93, D94, D96-97, D98, D106-08, D112-14, D117, D122-24, D350.[2] These individuals have "no choice but to breathe the air where [they] live[] and work[]" or to eat the food on their table. *LaFleur*, 300 F.3d at 270; D8-D9, D11-12; D101-102.

The pesticides at issue can cause severe neurological, developmental, and other disorders. *See* D6, D9, D12, D15-16, D28, D101-04. When EPA raises allowable exposure limits for these chemicals, people who live, work, and eat downwind or downstream will thus "undoubtedly" experience "increased levels" of exposure, practically "whenever the wind blows . . . in [their] direction." *LaFleur*, 300 F.3d at 270. Such increased exposure exacerbates health risks and

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denied, 526 U.S. 1146 (1999); *Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1234-35 (D.C. Cir. 1996).

[2] Petitioners have concurrently filed a volume of Declarations in Support of Standing, citations to which in this brief follow the form "D[page number]." This volume includes evidence submitted with Petitioners' August 3, 2006 Response to EPA's Motion to Dismiss, including the expert declarations of Gina Solomon, M.D., Adam M. Finkel, Sc.D., Margaret Reeves, Ph.D., and Karen Mountain, M.B.A., M.S.N., R.N., as well as additional percipient witness declarations of Petitioners' members and officers. The declarations volume also includes additional expert and percipient witness declarations that relate to subsequent EPA actions, as well as to a standing issue that EPA did not raise until its merits brief and which is addressed *infra*, at Section I.C.

uncertainty.[3] *See* D5-6, D9, D11-12, D15-16, D28-29, D30, D41, D57, D63-64, D84-88, D90, D91, D92, D107-08.

The Human Testing Rule[4] caused EPA to set higher pesticide exposure limits for the pesticides at issue. Promulgation of the Rule lifted Section 201's moratorium on EPA use of human toxicity experiments to set pesticide standards and, shortly after the Rule took effect, EPA began relying on such experiments to increase allowable exposure limits for these pesticides. For example, EPA increased allowable exposure levels for aldicarb, amitraz, dichlorvos, and methomyl – neurotoxins all – by as much as three, five, and even ten times the levels EPA would have set but for its use of these human studies. *See* D9-11, D12, D15, D18-19, D28-29, D31, D54-55, D162-166, D219, D225, D230-231, D381; *cf. Baur*, 352 F.3d at 637 n.11 (holding that evidence of post-filing events can "confirm that a plaintiff's fear of future harm is reasonable").

EPA's reliance on the Human Testing Rule to increase allowable pesticide exposure levels was not only a possible, but the predictable result of the Rule. When the Rule issued, EPA faced an imminent August 2006 deadline for

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[3] The precise level of risk posed by increased exposure is not itself a question of Article III significance. *See Baur*, 352 F.3d at 642-43; *cf. Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (holding that even a "perceptibl[e]" injury satisfied Article III).

[4] EPA used to refer to the subject of its rule as "Human Testing," *e.g.*, 70 Fed. Reg. 6661 (Feb. 8, 2005), and to call it the "Human Studies Rule," A1274. That name is more precise than EPA's new term, "Research Rule."

reregistering numerous pesticides and reassessing thousands of pesticide tolerances (i.e., deciding which pesticides and which food uses were sufficiently safe to continue). *See* 21 U.S.C. § 346a(q); 7 U.S.C. § 136a-1(g)(2)(A)(i). To meet that August deadline, EPA relied on human experiments that had already been conducted, and the results of which (purporting to justify a relaxation in pesticide protections) were thus known. *See, e.g.*, A156, A666, A704-06; D130; Wall Decl. in Supp. of Mot. to Complete Admin. R. (Sept. 28, 2006), Ex. B at 2 (EPA memo from July 2005 reciting how EPA could use dichlorvos human study to justify tenfold increase in exposure levels).

Moreover, EPA's promulgation of the Rule resulted in two critical changes to the way EPA set these pesticides standards. First, as noted above, the Rule lifted Section 201's moratorium on EPA use of human toxicity experiments. SPA1. Second, EPA's use of the experiments changed EPA's calculation of allowable exposure levels for a number of pesticides. Under EPA's standard risk assessment methodology, whenever EPA relies on only animal experiments to assess risk, it applies a tenfold safety factor to account for the prospect that humans are more susceptible than animals. A153; D3-5, D44-46, D49-51. Where EPA uses human experiments, it reduces or eliminates this safety factor. Thus, EPA's use of human studies predictably caused EPA to reduce or waive the tenfold safety factor and calculate significantly higher allowable exposure levels for these

pesticides. D3, D5, D28-29, D49-55. This expected result was, of course, precisely why the pesticide manufacturers began aggressively submitting human toxicity tests to EPA in the first place. *See* Pet'rs. Br. 13-14; A666.[5]

In light of this evidence, EPA's description of Petitioners' injury as "speculative" – or, with some rhetorical gusto, as "a hypothetical injury associated with the possibility of higher exposure levels that might be established in future EPA proceedings" – is perplexing. EPA Br. 1-2. The events that EPA calls "speculative" have in fact already occurred. EPA itself admits this, noting that "[t]he declarations and documents submitted by Petitioners related to recent EPA actions regarding tolerance levels demonstrate that this multi-step path was followed in the post-Research Rule actions cited by Petitioners." EPA Br. 25.

The harm to Petitioners' members here is thus far more certain than other, future harms this Court has found to satisfy Article III in previous cases, including a risk that EPA's approval of a flawed state permitting program might cause later increases in air pollution, *see NYPIRG*, 321 F.3d at 324, 325-26, and the risk from a regulation that increased the prospect of exposure to mad cow disease, a pathogen that had not yet been discovered in this country, *see Baur*, 352 F.3d at

[5] Because EPA's Human Testing Rule fails to adopt basic scientific safeguards recommended by the National Academy of Sciences, many of the human toxicity experiments considered by EPA lack the statistical power to detect adverse health effects that would be experienced across a wider population. A60-62; D6-7, D48, D59-61. When EPA relies on such studies, the result is an increase in risk to those exposed. *See id.*; *see also* D11, D15, D19, D29, D41, D63-64.

633-355, 642. EPA ignores this evidence and precedent, instead arguing that an injury is *always* too speculative – as a matter of law – if the challenged agency action is not the very last step in the causal chain. EPA Br. 21, 23, 27 & n.5. As we discuss in the next section, that theory has been rejected both by the Supreme Court and by this Circuit.[6]

B. Petitioners' Injuries Are Fairly Traceable to EPA's Rule

Uncontroverted evidence establishes that the Human Testing Rule changed EPA's pesticide standard setting process, causing EPA to waive a tenfold uncertainty factor and thus, predictably, to increase allowable exposure levels for pesticide to which Petitioners members are exposed. *See supra*, at Section I.A. EPA contends that despite this evidence, Petitioners cannot satisfy Article III's

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[6] Petitioners have standing to sue to protect their own organizational interests, as well as those of their members. Petitioners Pineros y Campesinos Unidos del Noroeste and Farm Labor Organizing Committee, AFL-CIO, for example, expend resources to investigate and respond to pesticide incidents affecting any of their numerous members. *See* D111, D113-16; D124-26. Petitioner Migrant Clinicians Network expends resources training the thousands of doctors, nurses, and other clinicians it represents to respond to such incidents. *See* D117-20. The resulting costs to Petitioners are established Article III injuries, *see Havens*, 455 U.S. at 379; *cf. Sierra Club v. Morton*, 405 U.S. 727, 737-38 (1972), that are "germane," *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977), to Petitioners' purposes. *See* D93, D99-100, D109, D117, D12. Indeed, the chance that one of Petitioners will expend resources to respond to such an incident is the aggregate of the risk to all of their thousands of members. *See* D109, D116, D117-19, D122; *cf. Utility Air Regulation Group v. EPA*, __ F.3d __, No. 05-1353, 2006 WL 3590194, *6 (D.C. Cir. Dec. 12, 2006) ("[G]iven the organization's large membership . . . we find it reasonable to infer that at least one member will suffer injury-in-fact.").

causation requirement because EPA's Rule was not the very last, or "operative," cause of their injury. EPA Br. 26-27 & n.5. Precedent says otherwise.

The Supreme Court expressly rejected EPA's argument a decade ago, in *Bennett v. Spear*, 520 U.S. 154 (1997). The *Bennett* plaintiffs sued the Fish and Wildlife Service ("FWS") over a biological opinion FWS provided to the Bureau of Reclamation ("Bureau"). *Id.* at 159. FWS challenged plaintiffs' standing, claiming that its biological opinion was not the "proximate cause" of the plaintiffs' anticipated injuries, which would occur (if at all) only after an "as yet unidentified" later decision by the Bureau. *Id.* at 168. The Court, per Justice Scalia, rejected that theory as "wrongly equat[ing] injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation."[7] *Id.* at 168-69; *see also Metropolitan Washington Airports Auth. v. Citizens for Abatement of Aircraft Noise*, 501 U.S. 252, 261-62, 264-65 (1991) (holding plaintiffs had standing to challenge a law that gave a review board power

[7] *Bennett* found the plaintiffs' injury "fairly traceable" to the FWS biological opinion because the facts supported that finding. The Court concluded that the FWS biological opinion would be "virtually determinative" of the Bureau's later decision because, if the Bureau disagreed with FWS, it would have to articulate the basis for its disagreement on the record and run the risk of being sued if it were wrong. 520 U.S. at 169, 170. Far from distinguishing the present case, this aspect of *Bennett* supports Petitioners' standing here. Petitioners' uncontroverted causation evidence – including the extensive testimony of one of the leading risk assessment experts in the country, *see* D37-41 – is both stronger and more direct than the circumstantial evidence *Bennett* found sufficient. Moreover, *Bennett* approached causation with particular care because the ultimate agency actor in that case, the Bureau, was not even a party. *Id* at 169. The same is not true here.

to veto a development plan because the power, although unexercised, had "influenced" plan adoption).

This Circuit, too, has rejected EPA's "operative cause" theory of standing. In *NYPIRG*, for example, the petitioners challenged EPA's authorization of New York's air pollution permit program.[8] 321 F.3d at 320-22, 324. EPA's approval of that program did not itself require or permit any increase in air pollution. Such a pollution increase would arise, if at all, only when New York later issued permits under its flawed program. This Court nevertheless found standing because EPA's authorization of the state program would increase the petitioners' members' "uncertainty" about pollution from nearby factories. *Id.* at 325-26. EPA's decision to permit the New York program was not the final step in the causal chain; EPA was not even the final actor. Yet standing existed because the members' injuries were "fairly traceable" to EPA's decision. Under *NYPIRG*, Petitioners here plainly have standing.

The two out-of-Circuit decisions on which EPA relies do not support a departure from this Court's precedent. In *Louisiana Environmental Action Network v. Browner*, 87 F.3d 1379 (D.C. Cir. 1996) ("*LEAN*"), the plaintiffs challenged an EPA rule that they feared would create an "enforcement gap," but

[8] EPA mischaracterizes *NYPIRG* as a challenge to an EPA decision that "regulated emissions of air pollutants from several facilities." EPA Br. 22. *NYPIRG* involved, and found standing for, three consolidated lawsuits, at least two of which EPA's characterization ignores. 321 F.3d at 324.

apparently presented no evidence that such an enforcement gap was likely, let alone likely where their members lived. *Id.* at 1383. At most, *LEAN* shows that an injury based on future agency action *can* be too speculative where the plaintiff introduces no evidence to prove causation; it does not show that such an injury is *always* too speculative, regardless of the evidence. As for *Shoreham-Wading River Central School District v. Nuclear Regulatory Commission*, 931 F.2d 102, 105 (D.C. Cir. 1991), its holding – that a plaintiff lacks standing to challenge an agency action if that action is a "but for" cause of the plaintiff's injury but not the "operative" cause – did not survive *Bennett*, 520 U.S. at 168-69, and has never been cited by any published decision of any court.

C. Petitioners Have Standing to Challenge the EPA's Failure to Regulate All Toxicity Experiments Covered by Section 201

Petitioners' uncontroverted evidence also establishes standing to challenge the Rule's failure to regulate human dosing pesticide toxicity experiments (including experiments on pregnant women and children) unless "intended" for EPA's consideration under FIFRA or FFDCA. EPA uses human toxicity experiments to set pesticide standards under other statutory programs, *see* Pet'rs. Br. 9-10, D29-33, as do other governmental agencies, *see, e.g.*, Pet'rs. Br. 28 & n.9; D33-34. Regulatory decisions under these other statutes increase Petitioners' members' risks of exposure in precisely the same way as do EPA's decisions under FIFRA and FFDCA.

For example, EPA regulates human exposure to pesticides under the Safe Drinking Water Act ("SDWA"), 42 U.S.C. § 300g-1(b). *See, e.g.*, 40 C.F.R. § 141.61(c) (setting SDWA maximum contaminant levels for numerous pesticides). Tens of thousands of Petitioners' members live in cities for which the source of drinking water has been contaminated with pesticides, including aldicarb, methomyl, and oxamyl – all chemicals for which EPA has received and is considering human dosing toxicity experiments. *See* D30-31, D91, D92, D95, D96-97, D98, D233 (¶ 4), D350. EPA is required by SDWA to reevaluate all existing drinking water standards every six years,[9] *see* 42 U.S.C. § 300g-1(b)(9), and to set new standards periodically, *see id.* at § 330g-1(b)(1)(B)(ii). It is predictable that when EPA does so, reliance on human experiments will lead to increases in allowable exposures levels, as has been true in EPA's FIFRA and FFDCA risk assessment process. 40 C.F.R. § 141.61(c); D28-29, D32-33.

Indeed, pesticide-industry human toxicity studies have already caused EPA to reduce drinking water protections for at least one pesticide. EPA set a drinking water standard for aldicarb, but later suspended that standard when the pesticide's manufacturer claimed that EPA had improperly relied on an animal study and should instead have relied on a particular human study. 57 Fed. Reg. 22178, 22179 (May 27, 1992). EPA reconsideration of that aldicarb drinking water

[9] EPA last reevaluated its oxamyl drinking water standard, for example, in 2003. *See* 68 Fed. Reg. 42908 (July 18, 2003).

standard is still pending, and EPA is considering human studies in that ongoing proceeding. *See id*. Had EPA's Human Testing Rule complied with Section 201, however, a different and more protective standard would govern EPA's use of human studies in that and other drinking water standard setting proceedings.[10]

Petitioners cannot wait to challenge EPA's failure to regulate the conduct and use of such experiments – which are covered by Section 201 but ignored by EPA's Rule, *see* Section II, *infra* – in assurance that a challenge could be launched when EPA uses such an experiment in a later proceeding. Were Petitioners to delay in challenging the unlawfully narrow scope of the Rule, EPA would no doubt argue that the FFDCA's sixty-day statute of limitations barred their litigation. *See* 21 U.S.C. § 346a(h)(1); *cf. NRDC v. Johnson*, 461 F.3d 164, 173-176 (2d Cir. 2006) (reading this FFDCA provision's judicial review exclusivity clause broadly).

Petitioners have challenged EPA's Rule in part to protect their members from predictable future risks resulting from the Rule's unlawfully narrow scope. As was the case in *NYPIRG*, 321 F.3d at 325-26, and *Baur*, 352 F.3d at 633-35, Article III poses no obstacle to this suit.

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[10] EPA's own aldicarb risk assessment shows that, when drinking water exposures are included, risks to every subgroup considered – the general population, infants, children age 1-2, and females age 13-49 – exceed the risk thresholds EPA would have used had it relied on an animal study rather than a human experiment. D29, D277 (defining level of concern), D279 (comparing exposure to human-based and animal-based levels of concern).

II. The Rule Violates Section 201's Blanket Ban on the Use of Pregnant Women and Children as Subjects in Pesticide Toxicity Experiments

Section 201 directed EPA to issue a rule, applicable to "intentional dosing human toxicity studies for pesticides," that "shall not permit the use of pregnant women, infants, or children as subjects." SPA1. There is no dispute that EPA did not adopt such a categorical rule. Instead, the Human Testing Rule regulates only those toxicity experiments that are "intended" to be submitted to EPA for consideration under FIFRA or FFDCA. SPA40 (§ 26.1201). The Rule's narrow scope violates Section 201 by, among other things, permitting many pesticide toxicity experiments on pregnant women and children and allowing EPA to consider such tests under statutes other than FIFRA and the FFDCA. These other statutes include the Safe Drinking Water Act and Clean Water Act, pursuant to which EPA also regulates human exposure to pesticides. *See* Pet'rs. Br. 9-10.[11]

EPA's contention that its narrowing construction conforms to Section 201's "object and policy," EPA Br. 30, fails for two reasons. First, the task of interpreting statutory language properly begins, not with an inquiry into "purpose," but with the statutory language itself. *See, e.g. Raila v. United States*, 355 F.3d 118, 120 (2d Cir. 2004) ("Statutory construction begins with the plain text, and, 'where the statutory language provides a clear answer, it ends there as well.'"

[11] Pesticides contaminate drinking water and surface waters regulated by the Safe Drinking Water Act and Clean Water Act when the pesticides run off agricultural fields or facilities where they have been applied.

(internal citation omitted)). "[A]lthough a court appropriately may refer to a statute's legislative history to resolve statutory ambiguity, there is no need to do so here," because the statutory text itself is clear. *Toibb v. Radloff*, 501 U.S. 157, 162 (1991). "Studies for pesticides" means just that – *i.e.*, "studies with respect to pesticides," *see* Random House Unabridged Dictionary 747 (2d ed. 1993) (defining "for") – not "studies for pesticides intended for EPA's consideration under FIFRA or FFDCA." Where, as here, "the statutory language is unambiguous and 'the statutory scheme is coherent and consistent,'" judicial inquiry "must cease." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) (internal citation omitted).

EPA originally acknowledged Section 201's obvious meaning. Shortly after Section 201's enactment, EPA issued a formal interpretative Guidance that concluded that the phase "studies for pesticides" encompassed studies *of* pesticides, even if not "submitted or otherwise available for consideration under [FIFRA or FFDCA § 408]." Wall Decl. in Supp. of Mot. to Complete Admin. R. (Sept. 28, 2006), Ex. A-1 at 14-15 (EPA Guidance setting out "[w]hat is meant by a study 'for pesticides'"). EPA's original administrative usage "confirms our understanding of the everyday sense of the term." *S.D. Warren Co. v. Maine Bd. Envt'l Prot.*, 126 S. Ct. 1843, 1849 (2006).[12]

[12] EPA's brief attempts to minimize the force of the Agency's original interpretation by labeling the Guidance "interim" and asserting it was drafted "broadly" to "avoid inadvertent noncompliance" with Section 201. EPA Br. 36.

Second, even if the statutory text were not clear, the legislative history belies EPA's claim that Congress intended to prohibit only those studies conducted and submitted for FIFRA and FFDCA purposes. EPA identifies no statement, from any Member of Congress, that Section 201 would allow dosing pregnant women and children with pesticides if the experiment was intended for EPA's use under other laws. When Senator Burns proposed an amendment that would have applied Section 201 to existing studies only if "submitted to the Agency under FIFRA," 151 Cong. Rec. S7552 (June 29, 2005), the Conferees rejected that approach, SPA1. *See* Pet'rs. Br. 21, 30.[13]

Instead, the legislative history shows that Section 201's proponents were appalled that researchers were dosing pregnant women and children with pesticides *at all*. Representative Solis, the lead House sponsor, summarized this sentiment, saying: "[i]t should never have taken place, the testing of pesticides on humans, particularly children." A647. Senator Boxer, the lead Senate sponsor, asked "what more of a moral issue can we be facing than allowing these students to have

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This explanation, which rests entirely on litigation counsel's say so rather than citation to the record, does not advance EPA's cause; the Agency obviously remains obliged to "avoid . . . noncompliance" with Section 201, inadvertent or otherwise.

[13] Nothing in the record remotely supports EPA's new assertion that Section 201 will deter development of mosquito repelling products. EPA Br. 34 n.10. Pesticides need not be applied to *children* to test their effectiveness against *mosquitoes*, and EPA has repeatedly made clear it does not need human studies to regulate pesticides in a manner that is protective of human health. *See* 151 Cong. Rec. H3671; A650.

chloropicrin pumped through their nostrils at a level 12 times higher than the safety level that OSHA, our Federal Government, says is safe?" 151 Cong. Rec. S7553 (June 29, 2005). Criticizing another study, involving infants, Section 201's co-sponsor, Senator Nelson, wondered: "Can anyone believe this is going on in the United States of America in the year 2005? . . . I certainly was not going to let that sort of thing go on in my State and it should not be going on in any State." 151 Cong. Rec. S7553-S7554 (June 29, 2005).

These floor statements reflect congressional recognition that the dangers of human dosing experiments have nothing to do with whether the study is intended for EPA's consideration under a particular statute. The dangers inhere in the experiments. This is why Section 201 expressly applies not only to EPA's "consider[ation]" of such experiments, but also to the studies' "conduct," regardless of the study sponsors' intentions.[14] SPA1.

[14] Some of the studies that horrified Section 201's proponents were no doubt intended for EPA consideration under the FQPA. This hardly proves EPA's claim, EPA Br. 31-33, that despite the clear language of Section 201, Congress meant *not* to regulate identical experiments conducted with a different intention. Indeed, a number of the studies that Section 201's sponsors condemned were conducted long before the FQPA was enacted. A705-06. EPA cites no evidence that these studies were "intended" for use under FIFRA or FFDCA.

III. The Rule Contravenes the National Academy's Proposed Principles

Section 201 required EPA to promulgate a rule that "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing." SPA1. The Academy's Report makes only one set of proposals; they are set forth in seventeen, enumerated Recommendations. Petitioners' opening brief demonstrated that EPA's Rule is inconsistent with these Recommendations, and EPA does not disagree.

Instead, EPA claims that when Congress referred to the "principles proposed by the 2004 report of the National Academy of Sciences," Congress was referring to three principles ("beneficence," "justice," and "respect for persons") identified in a 1979 document called the "Belmont Report." A1286. EPA contends that these three "principles" are also "contained in the NAS Report," EPA Br. 37, and "form the basis for *many* of" the Report's recommendations, EPA Br. 39 (emphasis added). From these premises, EPA urges the Court to conclude that the Belmont Report's principles are "the principles proposed" by the Academy, and adopted by Congress, even though neither the text of Section 201 nor its legislative history ever mention these principles.

A threshold difficulty with EPA's argument is that Congress did not require consistency with some subset of principles "contained in" (EPA Br. 37) the Academy's Report. Congress required consistency with the principles that Report

"proposed." SPA1. A "proposal" is, of course, a "recommendation." *Random House Unabridged Dictionary* 1551 (2d ed. 1993). The Academy explicitly set forth its "proposals" in its Recommendations. A129 ("Because of . . . the need to be specific about the proposals being made, the recommendations follow.").

By contrast, the Academy never "proposed" the Belmont principles, let alone proposed those principles as *the* sole principles of the Academy's Report. The Belmont Report was just one of the several "authoritative statements" that the Academy concluded *collectively* represented the (then-existing) "basic standards that govern human research in the United States." A127, 234; Pet'rs. Br. 46-47. Far from "proposing" these principles, however, the Academy found them too "unclear, indeterminate, inconsistent, and frequently contradictory" to provide appropriate guidance for toxicant research. A235. This was why the Academy offered its "own judgments," *id.*, as set forth in its Recommendations. EPA's selective adoption of the most "unclear" and "indeterminate" of the several pre-existing statements of principle would turn the Academy's work on its head.[15]

EPA's claim (EPA Br. 37) that the Academy's Recommendations do not set forth "principles" is also wrong. In one meaning, a "principle" is "a standard . . .

[15] EPA's unprincipled selectivity is highlighted by its implicit admission that the Belmont principles were not a basis for all of the Academy's proposals. EPA Br. 39. For example, the Belmont principles were never mentioned in the Academy's chapter setting forth scientific principles, which is not surprising, since the Belmont Report addresses ethics, not science. A189-206.

for guiding conduct or practice," *Random House Unabridged Dictionary* 1539 (2d ed. 1993). This meaning aptly describes the Academy's Recommendations. That this was the meaning Congress used in Section 201 is demonstrated by Section 201's other use of this word to refer to the "principles of the Nuremberg Code." EPA concedes that the Nuremberg Code's "principles" are the ten standards enumerated in that Code. A529. Notably, the Nuremberg Code's principles are specific, codified rules of conduct. They are similar in enumeration, structure, and detail to the Academy's Recommendations – and entirely dissimilar to the Belmont Report's vague invocations of "justice," "beneficence," and "respect." Thus, Congress' use of the phrase "principles proposed" to refer to the Academy's Recommendations is not only consistent with common usage, it is the only usage of "principles" that is consistent with Congress' other use of that same word, in the same sentence, to refer to the Nuremberg Code.

Nor does our reading of the statute render Section 201's requirement of an "*independent* Human Subjects Review Board," SPA1 (emphasis added), redundant with the Academy's recommendation of a "Human Studies Review Board," A258. The Academy proposed a Review Board "internal" to EPA and explicitly recommended that this Board *not* be "independent." A259. Congress' requirement of an "independent" board is thus not "redundant," EPA Br. 38, but reflective of Congress' disagreement with this single aspect of the Academy's proposals.

To be sure, Congress *could* have referred to the Academy's seventeen proposals as "Recommendations," rather than as "principles proposed," but there was no need for Congress to do so. The English language is sufficiently resilient to allow Congress to choose among words and phrases that, in context, convey the same meaning. In ordinary English, "principles proposed" means "recommended standards for guiding conduct." That phrase succinctly and accurately describes the Academy's Recommendations.

Congress' meaning is confirmed by the legislative history. The floor debates are replete with statements by Section 201's proponents that the law would require EPA to abide by the Academy's "recommendations." 151 Cong. Rec. H7019; 151 Cong. Rec. H7020-H7021; Pet'rs. Br. 44-45. The Belmont principles are not mentioned. This legislative history thus reinforces the textual analysis.

"Even for an agency able to claim all the authority possible under *Chevron*, deference to its statutory interpretation is called for only when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent." *General Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004). Here, the text and history of Section 201 do provide a "clear sense" that Congress intended EPA to conform to the Academy's Recommendations, not the Belmont principles. EPA's unreasonable interpretation should be rejected.

IV. The Rule Violates the Nuremberg Code and FIFRA Section 12

Section 201 requires EPA's Rule to be "consistent" with the Nuremberg Code. SPA1. In normal usage, "consistent" means "agreeing or accordant." *See Random House Unabridged Dictionary* 434 (2d ed. 1993). The Human Testing Rule, however, authorizes human experiments that are not consistent with, and in some cases violate, the Nuremberg Code. The Rule also contravenes FIFRA section 12(a)(2)(P). SPA2.

A. The Rule Authorizes Toxicity Experiments Without the Subject's Fully Informed, Comprehending, and Voluntary Consent

Petitioners' opening brief showed that EPA's Rule allows someone other than the human subject to "consent" to the experiment, in violation of the Nuremberg Code and FIFRA section 12(a)(2)(P); fails to require that the human subject be free of "any element . . . of constraint or coercion," in violation of the Nuremberg Code; and fails to ensure that the human subject "comprehen[ds]" the risks, also in violation of the Nuremberg Code. *See* Pet'rs. Br. 49-55; A529. EPA's defenses are unpersuasive.

EPA first suggests that all the studies with which Petitioners are concerned – studies that EPA admits contained "misleading statements in the informed consent materials" – are irrelevant because those studies "took place *prior*" to the Rule. EPA Br. 45 (emphasis in original). EPA misses the point. Section 201 does not only restrict EPA's consideration of experiments that may be conducted in the

future. It also restricts EPA's consideration of *existing* studies, including studies conducted before the Rule was promulgated. Section 201's text suggests no exception for EPA consideration of past studies, SPA1, and the legislative history makes clear Congress' specific purpose to stop EPA from using these studies. A647 (Rep. Solis) ("All of the studies currently pending before EPA . . . fall far short of the stringent criteria for EPA consideration outlined by the NAS and the Nuremberg Code, and required by this amendment."); 151 Cong. Rec. S7553 (June 29, 2005) (Sen. Boxer) (similar); 151 Cong. Rec. S7557 (June 29, 2005) (Sen. Burns) (critiquing Boxer amendment for prohibiting use of existing studies).

Nor does the Rule ensure prospective consistency with the Nuremberg Code. The Agency's lead argument is that because the Nuremberg Code's first principle uses the word "should," rather than "shall," most of the principle is optional. EPA Br. 46. Consistency with an optional principle would not be difficult. However, EPA's argument ignores the first sentence of this principle: "The voluntary consent *of the human subject* is absolutely essential." A529 (emphasis added). Consent by someone other than the human subject violates this standard.

EPA's argument would also eviscerate virtually the entire Nuremberg Code, as well as Congress' direction to conform to that Code. "Should" is the operative word in nine of the Nuremberg Code's ten principles – none of which use "shall." A529. That the Nuremberg Code uses the language of ethics ("should"), rather

than the mandatory language of law ("shall"), cannot mean that Congress intended compliance with its principles to be voluntary. If that were the case, the most fundamental requirements of the Code – including the principles that a human subject "should" be protected against death or disability (Principle 7) and "should" be able to withdraw from an experiment while it is underway (Principle 9) – would amount to little more than a nice idea.[16]

Petitioners do not, as EPA claims (EPA Br. 44), demand "exact correspondence" between EPA's Rule and the text of the Nuremberg Code. What Section 201 requires is substantive consistency. EPA's Rule allows experiments to be conducted that violate the Code. The Rule is therefore inconsistent with that Code and Section 201.[17]

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[16] EPA's "should" argument also fails because EPA did not articulate this rationale at any point during the Rulemaking. *See Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) (agency action "must be upheld, if at all, on the basis articulated by the agency itself"); *Gifford Pinchot Task Force v. U.S. Fish & Wildlife Serv.*, 378 F.3d 1059, 1072 n.9, 1074 (9th Cir.) (a court may "only rely on what the agency said in the record"), *amend. on other grounds*, 387 F.3d 968 (9th Cir. 2004).

[17] EPA's defenses to two of Petitioners' other concerns are equally unavailing. First, the Rule's direction only to "minimize the possibility of coercion or undue influence" plainly does not ensure that a human subject must "be able to exercise free power of choice, *without* . . . *any* element of . . . constraint or coercion," as required by the Nuremberg Code. An *element* of constraint can remain even after coercion has been "minimized" to the extent the circumstances (of, say, imprisonment) allow. Second, EPA's claim that its Rule ensures "comprehension" by human subjects ignores the only evidence on this issue before EPA, which was

Nor is EPA correct that "the issue of legal representatives providing consent on behalf of children . . . is not at issue." EPA Br. 47. EPA has placed such experiments at issue by declining to prohibit pesticide toxicity experiments on children unless the experimenter intends to submit the results for EPA's consideration under FIFRA or FFDCA. *See supra*, at Argument II. In any event, EPA's argument simply highlights the Rule's authorization of pesticide toxicity experiments on persons who are mentally infirm, incapacitated, or imprisoned, if a "representative" provides "consent." EPA defends this chilling proposition by arguing that the Declaration of Helsinki, Common Rule, and Belmont Report do not prohibit consent by a "representative." EPA Br. 47. EPA similarly argued, during the rulemaking, that ethical principles had "evolved," A1277, and that later statements of ethics provided "much more viable guidance" than the Nuremberg Code itself. A1182; *see also* EPA Br. 47. Congress required consistency with the Nuremberg Code, however, and EPA may not discard that Code whenever EPA believes it to be dated. *See* A647 (151 Cong. Rec. H7020 (July 28, 2005)

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the Academy's conclusion that the Common Rule standards that EPA's Rule adopted provide too little guidance to ensure comprehension. A244.

In any event, EPA's rationalizations of how the Rule conforms to the Nuremberg Code's "comprehension" and "without any element of . . . constraint" requirements come too late in the day. Neither explanation was ever articulated by EPA during the Rulemaking. A1277-78. When Petitioner objected that the draft rule failed to ensure full comprehension, for example, EPA ignored the comment. A1180-81. EPA's action "must be upheld, if at all, on the basis articulated by the agency itself" during the Rulemaking, not "counsel's post hoc rationalizations." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 50.

(statement of Rep. Solis) ("This amendment forbids the EPA from considering any intentional human dosing study unless it meets the minimum ethical and scientific safeguards outlined in . . . the 1947 Nuremberg Code adopted after World War II.")).

The Rule also is contrary to FIFRA section 12(a)(2)(P), 7 U.S.C. § 136j(a)(2)(P), which bars human pesticide experiments without the "fully informed" consent of "such human beings" on whom pesticides are tested. SPA2; Pet'rs. Br. 51-52, 53. Notwithstanding EPA's summary conclusion to the contrary, EPA Br. 48, the Rule obviously allows tests to proceed without the consent of "such human beings" when "consent" is given by a representative. The Rule is contrary to FIFRA section 12(a)(2)(P) and should therefore be set aside. *See* 5 U.S.C. § 706(2)(A).

B. The Rule Contravenes the Nuremberg Code's Requirement that Human Experiments Be Based on Prior Animal Studies

The Nuremberg Code allows human experimentation only if the experiment is "so designed and based on the results of animal experimentation . . . that the anticipated results justify the performance of the experiment." A 529. EPA's Rule, by contrast, authorizes human toxicity experiments without regard to whether they are (or are not) based on prior animal studies.

EPA's response, that it "has access to all *available* laboratory animal studies," simply begs the question. EPA Br. 51 (emphasis added). Neither the

Human Testing Rule nor any other authority cited by EPA actually requires that animal studies be "available" before a human experiment is conducted; EPA's implication that "the animal studies" are "required to be submitted under" the Rule, EPA Br. 51, is thus at best misleading and at worst untrue. Nor does the Rule require, as it should, that human experiments be based on prior animal studies. While EPA *may* review any animal studies that happen to be available, nothing in the Rule directs EPA to do so. A1278 (EPA acknowledgement that its rule does not address Nuremberg Code principle three "directly").

The Nuremberg Code sets forth a clear requirement that EPA's Rule ignores. In lieu of the Code's substantive standard, EPA offers process. Process is not substance, however. Nothing in the Rule directs EPA to ensure consistency with the Code, and EPA could as easily decline to do so. EPA's claim that the Rule's procedures *allow* EPA later to correct the Rule's substantive deficiency falls short.

C. The Rule Ignores the Nuremberg Code's Requirement that Human Experimentation Be Conducted Only When Necessary

The Nuremberg Code's second principle prohibits human experimentation unless the experiment is "such as to yield fruitful results . . . unprocurable by other . . . means of study, and not . . . unnecessary . . . ." A529. EPA's Rule contains no substantively consistent condition. Instead, EPA asserts that it will review experiments to ensure that "[r]isks to subjects are reasonable in relation to anticipated benefits." EPA Br. 52 (alteration in original). The Nuremberg Code's

second principle does not articulate a balancing test, however, but a bright line: Human experiments may not be conducted unless other types of studies cannot procure the information. Because the Rule allows experiments that would violate this principle, the Rule contravenes Section 201.

V. The Court Should Vacate and Remand the Human Testing Rule

This Court should vacate the Human Testing Rule rather than accepting EPA's invitation to leave the Rule in place while EPA revisits its flaws. EPA Br. at 54 n.16. The difference is important. Section 201 imposed a moratorium on EPA's conduct and use of intentional human dosing pesticide toxicity experiments until EPA promulgated a Rule that met certain standards. SPA1. This moratorium is not a "regulatory gap," as EPA suggests, EPA Br. 54 n.16; it is a ban. Petitioners do not "favor" EPA's issuance of a substantively inadequate regulation that lifts that ban on EPA conduct and use of human toxicity experiments.

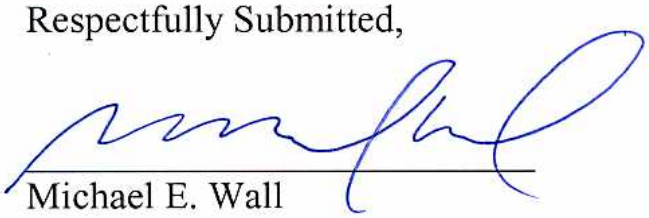
EPA's promulgation of the Human Testing Rule has had real, harmful consequences for Petitioners and their members. In the months after EPA promulgated the Rule, EPA relied on human dosing toxicity experiments to increase allowable pesticide exposure limits and to weaken public health protections. Had EPA *not* promulgated this Rule, the Agency could not have used the human studies to justify these weakened standards. If this Court vacates the

Rule, EPA will be obligated to revisit those standards. Petitioners therefore urge the Court to vacate the Rule at this time.

CONCLUSION

This Court should vacate the Human Testing Rule and direct EPA to issue a new rule in accordance with law.

December 14, 2006 Respectfully Submitted,

By: 

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Certificate of Compliance with Rule 32(a)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(ii) because it contains 6995 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2003 in a 14 point, Times New Roman font.

December 14, 2006

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that she is an employee in the San Francisco Office of the Natural Resources Defense Council, 111 Sutter Street, 20th Floor, San Francisco, CA, 94104; is a person of such age and discretion to be competent to serve papers; and that on December 14, 2006 she served copies of the attached:

- Petitioners' Reply Brief
- Declarations in Support of Petitioners' Standing

by causing said copies to be placed in a prepaid or postpaid envelope addressed to the persons hereinafter named, at the places and addresses stated below, which are the last known addresses, and by either delivering said envelope to Federal Express for delivery or depositing said envelope and contents in the United States Mail at San Francisco, California, or by facsimile, e-mail, or hand delivery, as stated below:

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: December 14, 2006

Erika Brekke

Angela Huskey/DC/USEPA/US	To	William Jordan, John Carley, Kelly Sherman
	cc	Steven Bradbury
02/11/2010 03:20 PM	bcc	
	Subject	Draft regulatory language

Attorney-Client Communication
Attorney Work Product
Pre-Decisional/Deliberative
Privileged and Confidential--Do Not Release

FYI...here's the draft regulatory language that we sent to the petitioners.

Draft regulatory language 020110.DOC

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[Code of Federal Regulations]
[Title 40, Volume 1]
[Revised as of January 1, 2008]
From the U.S. Government Printing Office via GPO Access

TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY

PART 26: PROTECTION OF HUMAN SUBJECTS--Table of Contents

Subpart K: Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

§ 26.1101 To what does this subpart apply?

(a)(1) Except as provided in paragraph (c) of this section, subpart K of this part applies to all research initiated after [insert effective date of amended rule] involving intentional exposure of a human subject to a pesticide if, at any time prior to initiating such research, any person who conducted or supported such research intended either to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA or to hold the results of the research for later inspection by EPA under any regulatory statute administered by EPA.

(2) For purposes of this section, substances that have no significant commercially valuable use as distributed or sold other than (i) use for pesticidal purpose (by itself or in combination with any other substance) or (ii) use for manufacture of a pesticide are considered pesticides. Substances that have multiple purposes, one or more of which may be for use in a pesticide, may or may not be considered pesticides. Such substances will not be considered pesticides, and t~~T~~his subpart does not apply to research with such substances, ~~a test material that is a pesticide~~ if the primary purpose of the research is to evaluate a property of a test material only relevant to its ~~when it is~~ use~~d~~ for non-pesticidal purposes. Examples include research to evaluate the efficacy of a test material as a human or animal drug.

(b) For purposes of determining a person's intent under paragraph (a), EPA may consider any available and relevant information. EPA shall rebuttably presume the existence of intent under the first sentence of paragraph (a) if:

(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA and, at the time the research was initiated, the results of such

research would be relevant to EPA's exercise of its regulatory authority with respect to that class of people, products, or activities.

(c) Unless otherwise required by the Administrator, research is exempt from this subpart if it involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from previously conducted studies, and if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(d) The Administrator retains final judgment as to whether a particular activity is covered by this subpart.

(e) Compliance with this subpart requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This subpart does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects. Reference to State or local laws in this subpart is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(g) This subpart does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

§ 26.1102 Definitions.

(a) *Administrator* means the Administrator of the Environmental Protection Agency (EPA) and any other officer or employee of EPA to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including Federal, State, and other agencies).

(c) *Initiation* of research involving human subjects is considered to occur as of the enrollment of the first subject in the research.

(d) *Research* means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this subpart, whether or not they are considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

(3) "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(f) *IRB* means an institutional review board established in accord with and for the purposes expressed in this part.

(g) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(h) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(i) *Research involving intentional exposure of a human subject* means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

(j) *Person* means any person, as that term is defined in FIFRA section 2(s) (7 U.S.C. 136), except:

(1) A federal agency that is subject to the provisions of the Federal Policy for the Protection of Human Subjects of Research, and

(2) A person when performing human research supported by a federal agency covered by paragraph (j)(1) of this section.

(k) *Pesticide* means any substance or mixture of substances meeting the definition in 7 U.S.C. 136(u) [Federal Insecticide, Fungicide and Rodenticide Act sec. 2(u)] ~~and any other substance or mixture of substances that is an ingredient in a pesticide or a degradate or metabolite of an ingredient of a pesticide~~.

§§ 26.1103-26.1106 [Reserved]

§ 26.1107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities which are presented for its approval. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as prisoners or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 26.1108 IRB functions and operations.

In order to fulfill the requirements of this subpart each IRB shall:

(a) Follow written procedures:

(1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(2) For determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;

(3) For ensuring prompt reporting to the IRB of proposed changes in research activity; and

(4) For ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Environmental Protection Agency of:

(1) Any unanticipated problems involving risks to human subjects or others;

(2) Any instance of serious or continuing noncompliance with this subpart of the requirements or determinations of the IRB; or

(3) Any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used (see Sec. 26.1110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 26.1109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this subpart.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec. 26.1116. The IRB may require that information, in addition to that specifically mentioned in Sec. 26.1116 be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with Sec. 26.1117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this subpart at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§ 26.1110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) (1) An IRB may use the expedited review procedure to review either or both of the following:

(i) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(ii) Minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Sec. 26.1108(c).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Administrator may restrict, suspend, or terminate, an institution's or IRB's use of the expedited review procedure for research covered by this subpart.

§ 26.1111 Criteria for IRB approval of research.

(a) In order to approve research covered by this subpart the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject, in accordance with, and to the extent required by Sec. 26.1116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by Sec. 26.1117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 26.1112 Review by institution.

Research covered by this subpart that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 26.1113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Administrator of EPA.

§ 26.1114 Cooperative research.

In complying with this subpart, sponsors, investigators, or institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 26.1115 IRB records.

(a) An IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB in the same detail as described in Sec. 26.1108(a) and Sec. 26.1108(b).

(7) Statements of significant new findings provided to subjects, as required by Sec. 26.1116(b)(5).

(b) The records required by this subpart shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of EPA at reasonable times and in a reasonable manner.

§ 26.1116 General requirements for informed consent.

No investigator may involve a human being as a subject in research covered by this subpart unless the investigator has obtained the legally effective informed consent of the subject. An investigator shall seek such consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject shall be in language understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. In seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in this subpart are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(d) Nothing in this subpart is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(e) The subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.

§ 26.1117 Documentation of informed consent.

(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject. A copy shall be given to the subject.

(b) The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by Sec. 26.1116. This form may be read to the subject, but in any event, the investigator shall give the subject adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by Sec. 26.1116 have been presented orally to the subject. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject. Only the short form itself is to be signed by the subject. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject, in addition to a copy of the short form.

§§ 26.1118-26.1122 [Reserved]

§ 26.1123 Early termination of research.

The Administrator may require that any project covered by this subpart be terminated or suspended when the Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.

§ 26.1124 [Reserved]

§ 26.1125 Prior submission of proposed human research for EPA review.

Any person or institution who intends to conduct or sponsor human research covered by Sec. 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by Sec. 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

(1) The potential risks to human subjects;

(2) The measures proposed to minimize risks to the human subjects;

(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and

(5) The balance of risks and benefits of the proposed research.

(b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.

(c) Information about how subjects will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.

Subpart L: Prohibition of Third-Party Research Involving Intentional Exposure of Human Subjects to a Pesticide who are Children or Pregnant or Nursing Women

§ 26.1201 To what does this subpart apply?

Subpart L applies to any research subject to subpart K of this part.

§ 26.1202 Definitions.

The definitions in Sec. 26.1102 apply to this subpart as well. In addition, the definitions at 45 CFR 46.202(a) through (f) and at 45 CFR 46.202(h) apply to this subpart. In addition, a *child* is a person who has not attained the age of 18 years.

§ 26.1203 Prohibition of research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child to a pesticide.

Notwithstanding any other provision of this part, under no circumstances shall a person conduct or support research covered by Sec. 26.1201 that involves intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a

child to a pesticide.

Subpart M: Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits to EPA ~~a report containing the results of any human research on or with a pesticide if:~~

~~(a) The report is submitted~~ after [insert effective date of amended rule] either of the following:~~, and~~

(~~a~~b) a report containing the results of any human research on or with a pesticide for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA, except FIFRA and FFDCA. For purposes of this paragraph, s~~The report is submitted for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA.~~
ubstances that have no significant commercially valuable use as distributed or sold other than (i) use for pesticidal purpose (by itself or in combination with any other substance) or (ii) use for manufacture of a pesticide are considered pesticides. Substances that have multiple purposes, one or more of which may be for use in a pesticide, may or may not be considered a pesticide. Such substances will not be considered pesticides, and this subpart does not apply to research with such substances, if the primary purpose of the research was to evaluate a property of a test material only relevant to its use for non-pesticidal purposes. Examples include research to evaluate the efficacy of a test material as a human or animal drug.

(b) a report containing the results of any human research on or with a pesticide for consideration in connection with an action that may be performed by EPA under FIFRA and FFDCA, regardless of the purpose of the research.

§ 26.1302 Definitions.

The definitions in sec. 26.1102 apply to this subpart as well.

§ 26.1303 Submission of information pertaining to ethical conduct of completed human research.

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such

research. To the extent available to the submitter and not previously provided to EPA, such information should include:

(a) Copies of all of the records relevant to the research specified by Sec. 26.1115(a) to be prepared and maintained by an IRB.

(b) Copies of all of the records relevant to the information identified in Sec. 26.1125(a) through (f).

(c) Copies of sample records used to document informed consent as specified by Sec. 26.1117, but not identifying any subjects of the research.

(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.

Subpart N [Reserved]

Subpart O: Administrative Actions for Noncompliance

§ 26.1501 To what does this subpart apply?

This subpart applies to any human research subject to subparts A through L of this part. References to State or local laws in this subpart are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

§ 26.1502 Lesser administrative actions.

(a) If apparent noncompliance with the applicable regulations in subparts A through L of this part concerning the operation of an IRB is observed by an officer or employee of EPA or of any State duly designated by the Administrator during an inspection. EPA may send a letter describing the noncompliance to the IRB and to the parent institution. EPA will require that the IRB or the parent institution respond to this letter within a reasonable time period specified by EPA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, EPA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, EPA may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and EPA will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, EPA may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§ 26.1503 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by EPA under Sec. 26.1502(a) and the Administrator determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Administrator may institute appropriate proceedings.

(b) The Administrator may disqualify an IRB or the parent institution from studies subject to this part if the Administrator determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects of research.

(c) If the Administrator determines that disqualification is appropriate, the Administrator will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing human research, covered by subparts A through L of this part, conducted under the review of the IRB. EPA will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and investigators, may also be sent a notice of the disqualification. In addition, EPA may elect to publish a notice of its action in the Federal Register.

(d) EPA may refuse to consider in support of a regulatory decision the data from human research, covered by subparts A through L of this part, that was reviewed by an IRB or conducted at an institution during the period of disqualification, unless the IRB or the parent institution is reinstated as provided in Sec. 26.1505, or unless such research is deemed scientifically sound and crucial to the protection of public health, under the procedure defined in Sec. 26.1706.

§ 26.1504 Public disclosure of information regarding revocation.

A determination that EPA has disqualified an institution from studies subject to this part and the administrative record regarding that determination are discloseable to the public under 40 CFR part 2.

§ 26.1505 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated to conduct studies subject to this part if the Administrator determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB has taken or plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the

standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under Sec. 26.1502(b)(4).

§ 26.1506 Debarment.

If EPA determines that an institution or investigator repeatedly has not complied with or has committed an egregious violation of the applicable regulations in subparts A through L of this part, EPA may recommend that institution or investigator be declared ineligible to participate in EPA-supported research (debarment). Debarment will be initiated in accordance with procedures specified at 2 CFR part 1532.

§ 26.1507 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other statutorily authorized proceedings or actions. EPA may, at any time, on its own initiative or through the Department of Justice, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. EPA may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

Subpart P: Review of Proposed and Completed Human Research

§ 26.1601 To what does this subpart apply?

This subpart applies to both of the following:

(a) Reviews by EPA and by the Human Studies Review Board of proposals to conduct new research subject to 40 CFR 26.1125, and

(b) Reviews by EPA after [insert effective date of the revised rule] and, to the extent required by sec. 26.1604, by the Human Studies Review Board of reports of completed research subject to 40 CFR 26.1701.

§ 26.1602 Definitions.

The definitions in sec. 26.1102 apply to this subpart as well.

§ 26.1603 EPA review of proposed human research.

(a) EPA shall review all proposals for new human research submitted under Sec. 26.1125 of this part in a timely manner.

(b) In reviewing proposals for new human research covered by subpart K, the Administrator shall consider and make determinations regarding the proposed research, including:

(1) Whether the research would be likely to produce data that address an important scientific or policy question that cannot be resolved on the basis of animal data or human observational research;

(2) Whether the proposed research is designed in accordance with current scientific standards and practices to:

(i) Address the research question;

(ii) Include representative study populations for the endpoint in question; and

(iii) Have adequate statistical power to detect appropriate effects.

(3) Whether the investigator proposes to conduct the research in accordance with recognized good research practices, including, when appropriate, good clinical practice guidelines and monitoring for the safety of subjects.

(c) In reviewing proposals for new research covered by subpart K, the Administrator shall consider and make determinations regarding ethical aspects of the proposed research including:

(1) Whether adequate information is available from prior animal studies or from other sources to assess the potential risks to subjects in the proposed research;

(2) Whether the research proposal adequately identifies anticipated risks to human subjects and their likelihood of occurrence, minimizes identified risks to human subjects, and identifies likely benefits of the research and their distribution.

(3) Whether the proposed research presents an acceptable balance of risks and benefits. In making this determination for research intended to reduce the interspecies uncertainty factor in a pesticide risk assessment, the Administrator shall consider Recommendation 4-1 of the National Research Council as contained in its report entitled Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues (2004).

(4) Whether subject selection will be equitable;

(5) Whether subjects' participation would follow free and fully informed consent;

(6) Whether an appropriately constituted Institutional Review Board or its foreign equivalent has approved the proposed research;

(7) If any person from a vulnerable population may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate;

(8) If any person with a condition that would put them at increased risk for adverse effects may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate;

(9) Whether any proposed payments to subjects are consistent with the principles of justice and respect for persons, and whether they are so high as to constitute undue inducement or so low as to be attractive only to individuals who are socioeconomically disadvantaged; and

(10) Whether the sponsor or investigator would provide needed medical care for injuries incurred in the proposed research, without cost to the human subjects.

(d) With respect to any research or any class of research, the Administrator may recommend additional conditions which, in the judgment of the Administrator, are necessary for the protection of human subjects.

(e) In reviewing proposals covered by this section, the Administrator may take into account factors such as whether the submitter has been subject to a termination or suspension under Sec. 26.123(a) or Sec. 26.1123 and whether the submitter or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Administrator, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

(f) When research covered by subpart K takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in subpart K. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration of Helsinki, issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if the Administrator determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in subpart K, the Administrator may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in subpart K.

(g) Following initial evaluation of the protocol, EPA shall submit the protocol and all supporting materials, together with the staff evaluation, to the Human Studies Review Board.

(h) EPA shall provide the submitter of the proposal copies of the EPA and Human Studies Review Board reviews.

§ 26.1604 EPA review of completed human research.

(a) When considering, under any regulatory statute it administers, data from completed research involving intentional exposure of humans to a pesticide, EPA shall thoroughly review the material submitted under Sec. 26.1303, if any, and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

(b) EPA shall submit its review of data from human research covered by subpart Q, together with the available supporting materials, to the Human Studies Review Board if EPA decides to rely on the data and:

(1) The data are derived from research initiated after April 7, 2006, or

(2) The data are derived from research initiated before April 7, 2006, and the research was conducted for the purpose of identifying or measuring a toxic effect.

(c) In its discretion, EPA may submit data from research not covered by paragraph (b) of this section to the Human Studies Review Board for their review.

(d) EPA shall provide the submitter of the research copies of the EPA and Human Studies Review Board reviews.

§ 26.1605 Operation of the Human Studies Review Board.

EPA shall establish and operate a Human Studies Review Board as follows:

(a) Membership. The Human Studies Review Board shall consist of members who are not employed by EPA, who meet the ethics and other requirements for special government employees, and who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology.

(b) Responsibilities. The Human Studies Review Board shall comment on the scientific and ethical aspects of research proposals and reports of completed research with human subjects submitted by EPA for its review and, on request, advise EPA on ways to strengthen its programs for protection of human subjects of research.

§ 26.1606 Human Studies Review Board review of proposed human research.

In commenting on proposals for new research submitted to it by EPA, the Human Studies Review Board shall consider the scientific merits and ethical aspects of the proposed research,

including all elements listed in section 26.1603(b) and (c) and any additional conditions recommended pursuant to sec. 26.1603(d).

§ 26.1607 Human Studies Review Board review of completed human research.

In commenting on reports of completed research submitted to it by EPA, the Human Studies Review Board shall consider the scientific merits and ethical aspects of the completed research, and shall apply the appropriate standards in Subpart Q.

Subpart Q: Ethical Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

§ 26.1701 To what does this subpart apply?

~~(b)~~(a) In actions taken under any regulatory statute, except FIFRA and FFDCA, t~~T~~his subpart applies to EPA's decisions whether to rely, in actions taken under any regulatory statute it administers, on scientifically valid and relevant data from research involving intentional exposure of human subjects to a pesticide. For purposes of this paragraph, substances that have no significant commercially valuable use as distributed or sold other than (i) use for pesticidal purpose (by itself or in combination with any other substance) or (ii) use for manufacture of a pesticide are considered pesticides. Substances that have multiple purposes, one or more of which may be for use in a pesticide, may or may not be considered a pesticide. Such substances will not be considered pesticides, and this subpart does not apply to research with such substances, if the primary purpose of the research was to evaluate a property of a test material only relevant to its use for non-pesticidal purposes. Examples include research to evaluate the efficacy of a test material as a human or animal drug.

(b) In actions taken under FIFRA and FFDCA, this subpart applies to EPA's decisions whether to rely on scientifically valid and relevant data from research involving intentional exposure of human subjects to a pesticide, regardless of the purpose of the research.

§ 26.1702 Definitions.

The definitions in Sec. 26.1102 and Sec. 26.1202 shall apply to this subpart as well.

§ 26.1703 Prohibitions

(a) Prohibition of reliance on scientifically invalid research involving intentional exposure of a human subject to a pesticide.

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EPA shall not rely on data from research involving intentional exposure of a human subject to a pesticide unless EPA determines that the data are relevant to a scientific or policy question important for EPA decision-making, that the data were derived in a manner that makes them scientifically reliable, and that it is appropriate to use the data for the purpose proposed by EPA. In making such determinations, EPA shall consider:

(1) Whether the research was designed and conducted in accordance with appropriate scientific standards and practices prevailing at the time the research was conducted;

(2) The extent to which the research subjects are representative of the populations for the endpoint or endpoints in question; and

(3) The statistical power of the data to support the scientific conclusion EPA intends to draw from the data

(4) In a study that reports only a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), whether a dose level in the study gave rise to a biological effect, thereby demonstrating that the study had adequate sensitivity to detect an effect of interest.

(b) Prohibition of reliance on research involving intentional exposure to a pesticide of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children.

Except as provided in Sec. 26.1706, EPA shall not rely on data from any research involving intentional exposure to a pesticide of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults not covered by section 26.1705.

(a) This section applies to decisions covered by section 26.1701 that are not covered by section 26.1705.

(b) Except as provided in Sec. 26.1706, EPA shall not rely on data from any research involving intentional exposure of any human subject to a pesticide, where that research was not covered by subparts A through L, if there is clear and convincing evidence that the conduct of the research was fundamentally unethical (e.g., the research was intended to seriously harm participants or failed to obtain informed consent), or was deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. This prohibition is in addition to the prohibitions in Sec. 26.1703.

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults initiated after April 7, 2006, and subject to subparts A through L or another codification of the Common Rule.

(a) This section applies to decisions covered by section 26.1701, if the research on which EPA intends to rely meets both of the following conditions:

(1) the research was initiated after April 7, 2006.

(2) the research was subject, at the time the research was conducted, either to subparts A through L of this part or to another codification of the Basic Policy for the Protection of Subjects in Human Research Conducted or Supported by a Federal Agency (generally referred to as the "Common Rule").

(b) Except as provided in Sec. 26.1706, EPA shall not rely on data from any research, unless EPA determines that the research was conducted in substantial compliance with one of the following:

(1) all applicable provisions of subparts A through L of this part or another codification of the Common Rule, whichever is applicable.

(2) under procedures at least as protective of subjects as those in subparts A through L of this part or another codification of the Common Rule, whichever is applicable, if the research was conducted in a foreign country.

(c) Except as provided in Sec. 26.1706, EPA shall not rely on data from any research, unless EPA determines that the research was conducted in substantial compliance with one of the following:

(1) a proposal that was found to be acceptable under Sec. 26.1603(c), and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. If EPA discovers that the submitter of the proposal materially misrepresented or knowingly omitted information that would have altered the outcome of EPA's evaluation of the proposal under Sec. 26.1603(c), EPA shall not rely on that data.

(2) a proposal that would have been found to be acceptable under Sec. 26.1603(c), if it had been subject to review under that section, and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

(d) This prohibition is in addition to the prohibitions in Sec. 26.1703.

§ 26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

This section establishes the exclusive criteria and procedure by which EPA may decide to rely on data from research that is not acceptable under the standards in §§ 26.1703 through 26.1705. EPA may rely on such data only if all the conditions in paragraphs (a) through (d) of this section are satisfied:

(a) EPA has obtained the views of the Human Studies Review Board concerning the proposal to rely on the otherwise unacceptable data,

(b) EPA has provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data,

(c) EPA has determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health, such as a limitation on the use of a pesticide, than could be justified without relying on the data, and

(d) EPA publishes a full explanation of its decision to rely on the otherwise unacceptable data, including a thorough discussion of the scientific and ethical deficiencies of the underlying research and the full rationale for finding that the standard in paragraph (c) of this section was met.

Angela Huskey/DC/USEPA/US

01/03/2008 10:53 AM

To William Jordan, John Carley
cc Lee Tyner, Philip Ross
bcc
Subject Hearing scheduled for human studies case

I have attached the notice for the hearing in the human studies rule case. It is scheduled for January 17 in the Second Circuit Court of Appeals in NYC. Each side gets eight minutes to present its argument.

Notice of Hearing Date.pdf

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UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
THURGOOD MARSHALL U.S. COURT HOUSE
40 FOLEY SQUARE, NEW YORK, N.Y. 10007

Catherine O`Hagan Wolfe
CLERK OF COURT

Date: 12/7/07 Docket **06-0820-ag**
Short Title: Natural Resources Defense Council v. United States
Agency Number: 40 CFR Agency: Environmental Protection Agency

NOTICE OF HEARING DATE

Date of Hearing: Thursday, January 17, 2008
Time Allotted for Oral Argument: 8 mins per side

The above referenced appeal is scheduled for oral argument on the day indicated in the **Ceremonial Courtroom (9th Floor)** , Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, Manhattan, New York City.

Court convenes promptly at 10:00 a.m. Counsel and non-incarcerated pro se litigants must be present for argument unless earlier excused. Motions to adjourn argument must be promptly made and will be granted for grave reason only.

Counsel and non-incarcerated pro se litigants presenting oral argument must register with the courtroom deputy no later than 9:30 a.m.. Please be advised that, due to the technical difficulties, we are unable to provide offsite Video Argument until further notice. It is hoped that we will again be able to offer this convenience in the future.
Counsel and non-incarcerated pro se litigants may seek the Court`s permission to waive oral argument by submitting a letter request to the Office of Clerk (attention Calendar Deputy) not later than five days before the hearing week.

Report all settlements to the Calendar Deputy as soon as effected. Ordinarily, and subject to the ruling of the presiding judge, motions or stipulations to withdraw with prejudice will be granted without appearance by counsel, but motions or stipulations to withdraw without prejudice filed within three business days of the argument will be considered at the time of argument, with counsel present and prepared to argue the merits.

CATHERINE O`HAGAN WOLFE, Clerk

Complete Items below and return copy of entire form to the Clerk`s Office

Name of the Attorney/Pro Se Presenting argument:
Firm Name (IF APPLICABLE):
Current Telephone Number:
The above named Attorney Represents:
( ) APPELLANT-PETITIONER ( ) INTERVENOR
( ) APPELLEE-RESPONDENT ( ) AMICUS CURIAE

Date: _____ Signature: _____

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
THURGOOD MARSHALL U.S. COURT HOUSE
40 FOLEY SQUARE, NEW YORK, N.Y. 10007

Catherine O'Hagan Wolfe
CLERK OF COURT

NOTICE TO THE BAR

Offsite Video Argument. Please be advised that, due to the technical difficulties, we are unable to provide offsite Video Argument until further notice.
It is hoped that we will again be able to offer this convenience in the future.

Audio Tape of Argument. An audio tape of an argument may be purchased for $26 per tape by written request to the Clerk. The request should include the case name, the docket number and the date or oral argument. Tapes will be delivered by first class mail unless the request instructs to hold for pick-up or requests Federal Express Service, in which case a Federal Express account number and envelope must be provided.

Court Reporters. Parties may arrange - at their own expense - for an official court reporter to transcribe argument from a copy of the hearing tape or to attend and transcribe the hearing directly. A party must first obtain written consent from opposing counsel - or move the Court for permission - to have the court reporter attend and transcribe the hearing and must provide the calendar clerk written notice, including the name, address and telephone number of the attending reporter and, if applicable, the reporting firm at least one week prior to the hearing date.

An original and three (3) copies of the transcript **must** be submitted to the Clerk for approval by the panel that heard the case; transcripts will not be officially filed until approved.

Interpreter Services for the Hearing Impaired. Counsel requiring sign interpreters or other hearing aids must submit a written request to the Calendar Team at least two weeks before oral argument.

Angela Huskey/DC/USEPA/US	To	William Jordan
	cc	John Carley
10/12/2006 01:50 PM	bcc	
	Subject	Fw: Brief if Amici Curiae in Natural Resources Defense Council v. Uni ted States Environmental Protection Agency, Docket Nos. 06-0820-ag(, 06 -1895-ag(con), 06-2149-ag(con), 06-2360-ag(con)

FYI....

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----- Forwarded by Angela Huskey/DC/USEPA/US on 10/12/2006 01:50 PM -----

"Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ. GOV>	To	Angela Huskey/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA
10/11/2006 04:58 PM	cc	
	Subject	Brief if Amici Curiae in Natural Resources Defense Council v. Uni ted States Environmental Protection Agency, Docket Nos. 06-0820-ag(, 06 -1895-ag(con), 06-2149-ag(con), 06-2360-ag(con)

-----Original Message-----
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Sent: Wednesday, October 11, 2006 2:52 PM
To: briefs@ca2.uscourts.gov
Cc: Greenberg, Alan (ENRD); zaringd@wlu.edu; tai2@wisc.edu;
acolangelo@nrdc.org; mwall@nrdc.org
Subject: Brief if Amici Curiae in Natural Resources Defense Council v.
Uni ted States Environmental Protection Agency, Docket Nos. 06-0820-ag(,
06 -1895-ag(con), 06-2149-ag(con), 06-2360-ag(con)

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Amicus Brief, 06-0820-ag.pdf

06-0820-ag(L),
06-1895-ag(CON), 06-2149-ag(CON), 06-2360-ag(CON)

United States Court of Appeals
for the
Second Circuit

NATURAL RESOURCES DEFENSE COUNCIL, INC., PESTICIDE ACTION NETWORK NORTH AMERICA, PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE, PHYSICIANS FOR SOCIAL RESPONSIBILITY-SAN FRANCISCO, FARM LABOR ORGANIZING COMMITTEE, AFL-CIO, and MIGRANT CLINICIANS NETWORK,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

ON PETITION FOR REVIEW OF AN ORDER OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BRIEF OF AMICI CURIAE SENATOR BARBARA BOXER, SENATOR BILL NELSON, CONGRESSMAN HENRY A. WAXMAN, and CONGRESSWOMAN HILDA SOLIS IN SUPPORT OF PETITIONERS

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INTEREST OF THE AMICUS CURIAE

Amici Senator Barbara Boxer, Senator Bill Nelson, Congressman Henry A. Waxman, and Congresswoman Hilda Solis urge the United States Court of Appeals for the Second Circuit to rule in favor of petitioners. This case turns on whether the EPA's Human Testing Rule, 71 Fed. Reg. 6138-01 (Feb. 6, 2006), encoded at 40 C.F.R. Parts 9 and 26, is inconsistent with the mandate provided by Congress in the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, § 201, Pub. L. 109-54, 119 Stat. 499. Amici were sponsors, co-sponsors, or supporters of the relevant provisions in the Senate and House of Representatives, and have an interest in ensuring that EPA observes both the letter of the statute and its intent.

ARGUMENT

Congress passed a law requiring EPA to promulgate its human testing rule because of the realization that without government controls, humans could be dosed with pesticides without their consent in an effort to weaken safety standards for those pesticides - or at least their consent in any real, freely given sense. Congress was concerned about the potential for human subjects to be injured through their participation in pesticide studies. Congress was particularly concerned about pregnant women, infants, and

children being induced into participating as human guinea pigs. Not only are these subpopulations potentially more sensitive to the effects of pesticides, but pesticide registrants may have a natural desire to conduct research on these subpopulations given that actual data could result in significantly more lenient regulatory standards.

Because EPA's rule fails to prevent this sort of testing, despite Congress's clear instructions to the contrary, we file this amicus brief in support of petitioners. Because EPA's rule is inconsistent with Congress's statutory guidance and the very purpose of Congress's decision to legislate, it must be vacated and remanded.

I. EPA Failed To Follow Congress's Clear Intent To Prohibit Pesticide Testing On Pregnant Women And Children.

The plain language of the statute establishes that Congress wanted pesticide testing on pregnant women, infants, and children banned. Congress directed EPA to prohibit "the use of pregnant women, infants, or children as subjects." § 201. The conference report indicated that "[c]oncern is particularly acute for pregnant women, fetuses, and children." H. Rep. No. 109-188 (2005). Congress acted because, as co-sponsor Rep. Hilda Solis noted, "[i]ntentional human toxicity testing has a troubling history that includes manipulation and abuse of the most vulnerable members of society." 151 Cong. Rec. H7018, 7021 (daily ed. July 28, 2005).

Accordingly, as Senator Barbara Boxer explained**,** a comprehensive regulatory scheme was crucial if "one cares about protecting children and families." 151 Cong. Rec. S7552, 7554 (daily ed. June 29, 2005) (statement of Sen. Boxer).

EPA's rule fails to implement the ban required by Congress. Instead, the rule only prohibits the use of data collected from pesticide experimentation on pregnant women, infants, and children for certain purposes. *See* 40 C.F.R. §§ 26.1701, 26.1702, & 26.1706 (2006).

Specifically, Congress did not limit its instructions to EPA to cover actions pursuant to only two of the many statutes that the agency administers. The statute says that "[s]uch rule shall not permit the use of pregnant women, infants or children as subjects." § 201. The EPA regulation, in contrast, only provides that its regulations "appl[y] to EPA's decisions whether to rely on its actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. § 136 et seq.) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 346a)." Since EPA's regulation fails by its own terms to apply the ban to its other programs for which human testing may be permissible – and EPA might consider such studies pursuant to its regulatory authority under the Safe Drinking Water Act and the Clean Water Act, for example – it is inconsistent with that

instruction. *See Yellow Transp., Inc. v. Michigan*, 537 U.S. 36, 45 (2002) ("If the statute speaks clearly to the precise question at issue, Congress must give effect to the unambiguously expressed intent of Congress.") (internal quotation marks omitted); *see also Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-843 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

Congress did not, in short, limit its statutory instructions to FIFRA and the FDCA. But because EPA interpreted its instructions as limited to those two regulatory programs, its rule violates the plain meaning of Section 201.

Congress legislated comprehensively because EPA itself has an inconsistent record on the protection of pregnant women, infants and children from the harms of human testing. The agency planned a joint federal-industry study to test the effect of chemicals on Florida children from newborn to three years old as part of the Children's Environmental Exposure Research Study (CHEERS). Michael Janofsky, *Nominee Challenged Over Program on Pesticides*, New York Times, Apr. 7, 2005**,** at A19. In exchange for participation in these tests, EPA planned to offer participating families $970, a free video camera, a T-shirt, and a framed

certificate of appreciation. David DeCamp, *EPA Drops Contested Pesticide Study*, Florida Times, April 9, 2005.

Congress found EPA's conduct deeply troubling. Florida senator Bill Nelson declared that he had had a "bellyful of this kind of stuff to come in on the citizens of the State of Florida, and I want it stopped." 151 Cong. Rec. S7554, 7554 (daily ed. June 29, 2005) (statement of Sen. Nelson). Congressman Sanford Bishop characterized CHEERS as "a trifecta of unethical, immoral, and unscientific research," 151 Cong. Rec. H3651, 3670 (daily ed. May 19, 2005) (statement of Rep. Bishop), and many others agreed.[1] Congress's concerns are, of course, well-grounded in established science, as well as ethics. More than a decade before EPA developed the CHEERS program, the National Academy of Sciences raised concerns that exposure of children to pesticides like that involved in the CHEERS study may cause "acute organophosphate pesticide poisoning." *See* U.S. House of Representatives, Committee on Government Reform—Minority Staff Special Investigations Division and United States Senate, Office of Senator Barbara Boxer, Environmental Staff, *Human Pesticide Experiments*, at 10

[1] *See also* 151 Cong. Rec. H7018, 7021 (July 28, 2005) (statement of Rep. Solis) (noting that "the Solis-Bishop amendment is supported by environmental and diverse religious organizations and among more than 80,000 others who have written to me saying they oppose the CHEERS study and support a moratorium on this type of testing.")

(June 2005), available at http://www.democrats.reform.house.gov/Documents/20050627115401-68567.pdf. (last visited Oct. 2, 2006) (A678[2]) [hereinafter *Human Pesticide Experiments*].

The CHEERS study provided unethical incentives and misleading disclosures and was much more than simply an observational study. Through the study, EPA directly encouraged and endorsed the exposure of very young children to toxic pesticides, placing them in harm's way and changing the status quo.

Congress accordingly tried to make sure that its intention to ban testing on pregnant women, infants, and children was very clear. The floor statements of the sponsors and supporters of the bill reaffirm the intent that EPA's implementation ignores. "A [floor] statement of one of the legislation's sponsors ... deserves to be accorded substantial weight in interpreting the statute." *Federal Energy Administration v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976); *see also American Trucking Ass'n, Inc. v. ICC*, 697 F.2d 1146, 1149 (D.C. Cir. 1983) (Scalia, J.) (relying on floor statements as part of the relevant legislative history of a statute); *Southeast*

[2] Citations to 'A___' are to the Appendix filed by Petitioners with their Opening Brief.

Shipyard Ass'n v. United States, 979 F.2d 1541, 1546 (D.C. Cir. 1992) (relying on floor debate to establish legislative intent).

Senator Bill Nelson observed that "[a]ny exposure of an infant child or a pregnant woman to a toxin basically should be prohibited, even in doses that are not expected to do any harm." 151 Cong. Rec. S7552, 7554 (daily ed. June 29, 2005) (statement of Sen. Nelson). He did so because, as he explained, "[t]he human testing of pesticides offers no therapeutic benefit." *Id.* Congressman Alcee Hastings noted that the legislation Congress passed "stops EPA from intentionally exposing pregnant women and children to pesticides." 151 Cong. Rec. H6941, 6942 (daily ed. July 28, 2005) (statement of Rep. Hastings)**.**

EPA's failure to follow Congress's clear instructions, given in both the language of the statute and floor debates, prohibiting pesticide testing on pregnant women, infants, and children is sufficient reason to vacate and remand the rule to the agency.

II. Congress Intended Consistency Between the Rule and the Seventeen Principles Set Forth in the 2004 National Academy of Sciences Report, Not the More General "Belmont Principles."

Section 201 was Congress's attempt to set minimum ethical and scientific requirements for EPA's human testing rule. Congress recognized that in absence of guidelines, EPA had been reviewing "over 20 human

dosing studies . . . [that] routinely violate ethical and scientific standards laid out in the Nuremburg Code, the Declaration of Helsinki, the 'Common Rule,' and the National Academy of Sciences recommendations on human testing." *See* 151 Cong. Rec. S7553 (daily ed. June 29, 2005) (statement of Sen. Boxer) (describing statements made prior to Conference supporting two competing amendments considered by the Senate, one also applying to "third-party intentional human dosing studies for pesticides"). Accordingly, Congress sought to constrain the EPA's discretion by putting something "in place that would guide these experiments" and EPA's use and consideration of them. *See id.*

Congress incorporated the principles of the 2004 NAS report into the protections it wanted EPA to provide test subjects. In fact, it said in Section 201 that the EPA rule "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences." The only exceptions to strict compliance with that report would be for occasions where the express language of section 201 provided for other, independent protections, such as the ban on the use of pregnant women, infants, and children as test subjects. This report contained seventeen concrete "recommendations to strengthen oversight and provide guidance for the use of intentional human dosing studies," A129, which were developed in response to similar concerns as

those before us now, A125-27. These recommendations ranged from issuing guidelines for determining whether intentional human dosing is scientifically valid, A130, to developing best practices for informed consent, A135-36. Moreover, these recommendations were purposefully specific, not general. *See* A129 ("Because of the complexity of the issues considered by the committee and the need to be specific about the proposals being made, the recommendations follow.").

But the EPA failed to comply with the legislative mandate to follow the seventeen recommendations of the 2004 NAS Report. Instead, the EPA relied on "'fundamental ethical principles' identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) in its report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the 'Belmont Report')." 71 Fed. Reg. 6138, 6164. In other words, according to the EPA, "principles proposed in the 2004 report of the National Academy of Sciences" refers not to the 2004 NAS Report itself, but to a report mentioned only 12 times within the 208 pages of the 2004 NAS Report. *See* A108-331, *available at* http://darwin.nap.edu/ books/0309091721/html/ (2004) (using search term "Belmont"). Such a conclusion contravenes the plain language of Congress, which nowhere mentioned the report EPA used,

and is unsupported by either traditional statutory analysis or the legislative history. *Chevron U.S.A., Inc.*, 467 U.S. at 842-43 (examining "whether Congress has directly spoken to the precise question at issue" to determine whether to uphold an agency's interpretation of a statute); *see also id.* at 843 n.9 (applying traditional tools of statutory construction). Indeed, aside from conflicting with Congress's clear intent, EPA's sole reliance on the Belmont Report is beyond the scope permitted by Congress. *See id.* at 843-44 (allowing a rule to stand only if it is based on a permissible construction of the authorizing statute). Accordingly, this Court should set aside the human testing rule.

A. Traditional Principles Of Statutory Interpretation Demonstrate That Congress Intended Consistency With The Seventeen Recommendations 2004 NAS Report.

In requiring EPA to rely upon the "principles proposed in the 2004 report of the National Academy of Sciences," § 201, Congress intended EPA to base its rule on the seventeen enumerated scientific and ethical recommendations of the NAS Report. It had no intention of allowing the vague language of the Belmont Report to supersede the seventeen concrete recommendations of the NAS Report. While the Belmont Report is referenced in the 2004 NAS Report, neither the Belmont Report nor any principles contained in it are "proposed" in the NAS Report in the sense that

the NAS offered them as "suggestions" or "offerings." *Random House Unabridged Dictionary* 1551 (2d ed. 1993) (defining "propose" as "to offer or suggest (a matter, subject, case, etc.) for consideration, acceptance, or action"). Instead, any principles contained in the Belmont Report were proposed in 1979 by the National Commission. A1286-87; A172-73 (identifying as "basic ethical principles" the concepts of "respect for persons," "beneficence," and "justice" as being put forth by the National Commission).

Indeed, the NAS recognized that it was not "proposing" any of the principles contained in the Belmont Report, in contrast to its seventeen "proposals," which did reflect its "own judgments." A235. The NAS consistently describes the Belmont Report as containing a separate set of principles apart from NAS's own,[3] even though the NAS recognized that the NAS Report may "draw[] on," A234, both the Belmont Report and other

[3] EPA's attempt to characterize the NAS as "mak[ing] the point clearly that they did not propose new principles," 71 Fed. Reg. 6138, 6164, is misleading. Although the NAS did acknowledge that it "was not required to invent the basic *standards* that govern human research in the United States," A127, 156 (emphasis added), the NAS Report focused on determining "how those standards should be applied in the particular case of intentional human dosing studies conducted by third parties for EPA regulatory purposes." A128. In doing so, the NAS recognized "the need to be specific," and thus set forth a series of seventeen new "recommendations to strengthen oversight and provide guidance for the use of intentional human dosing studies at EPA." A129.

"authoritative statements of principle," A127. For example, the NAS Report describes the Belmont Report as the creation of the National Commission. *See* A172 ("The National Commission is perhaps best known for its Belmont Report"). Similarly, the NAS treats the principles of "respect for persons, beneficence and justice" as not its *own* principles, but those contained in the Belmont Report. *See, e.g.*, A173 ("The Belmont Report recommended that additional attention be given to the equitable selection of participants.").

Bare reliance on "respect for persons," "beneficence," and "justice"—without the recommended specificity provided by the NAS Report—must also be rejected as inconsistent with Congress's mandate. Congress stated that the EPA's rule should be "consistent with the principles proposed" in the 2004 NAS Report. § 201. The 2004 NAS Report, in turn, rejected complete reliance on earlier sources of principles, such as the Belmont Report, because they were "frequently unclear, indeterminate, inconsistent, and even contradictory" in terms of providing sufficient guidance to EPA. A235. Thus the NAS proposed its own set of recommendations—recommendations that covered both "scientific and ethical principles"—and even recommended a procedural framework for their implementation. A168. These recommendations are what Congress meant EPA to rely upon, not the "general prescriptive judgments" in the Belmont Report.

Moreover, the "general prescriptive judgments" of the Belmont Report, A1288, cannot reasonably be conflated with the seventeen concrete recommendations—such as developing and disseminating to Institutional Review Boards, investigators, and sponsors a list of best practices for informed consent, A245, and operating on the "strong presumption that data obtained *after* implementation of the new rules that do not meet the ethical standards described in this report will not be considered," A250 (emphasis in original)—of the NAS Report. *See Sierra Club v. EPA*, 356 F.3d 296, 306 (D.C. Cir. 2004) (recognizing that an agency cannot take an action that abandoned or supplanted the model upon which Congress mandated the action be "based"). The Belmont Report provides "ethical" principles, rather than the scientific and ethical principles of the NAS Report. A1288-89.

This plain-language interpretation of Congress's mandate as requiring EPA to rely upon the seventeen recommendations in the NAS Report is further supported by the interpretive canon of deriving the meaning of a word "from the company it keeps." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995). Here, Congress specifically listed two sets of "principles" with which EPA's rule must be consistent: the 2004 NAS Report, and the "Nuremberg Code with respect to human experimentation." § 201. The

Nuremburg Code, much like the 2004 NAS Report, contains ten standards providing specific directives to guide human experiments: from emphasizing the absolute essentiality of voluntary consent," A529, to allowing the conduct of human experiments only if the studies provide results "unprocurable by other methods or means of study," *id.*, to avoiding "all unnecessary physical and mental suffering and injury." *Id.* The structural similarity of the ten principles of the Nuremberg Code with the seventeen principles in the 2004 NAS Report (and the structural dissimilarity of the principles in the Nuremburg Code with the three general concepts of the Belmont Report) further establishes Congress's intent that EPA rely on the actual principles set forth by the NAS Report, not the NAS's report minimal reference to the Belmont Report. Otherwise, "principles" would be ascribed a meaning "so broad that it is inconsistent with its accompanying words, thus giving 'unintended breadth to the Acts of Congress.'" *Gustafson*, 513 U.S. at 575 (citing *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961)).

B. The Legislative History Also Supports The Use Of The Seventeen Recommendations In The 2004 NAS Report.

The legislative history behind the Congressional mandate further establishes its intent that EPA rely on the seventeen standards set forth by the NAS in its 2004 Report, rather those described by the National Committee in its Belmont Report. *See Chevron*, 467 U.S. at 843 n.9 (urging

reliance on "traditional tools of statutory interpretation," including legislative history); *see Babbitt v. Sweet Home Chapter of Cmty for a Great Or*, 515 U.S. 687, 704-08 (1995) (examining Senate and House Reports to hold that Congress intended the challenged "take" provision "to apply broadly to cover indirect as well as purposeful actions"). The discussions in the House debate regarding the Conference Report to which Section 201 was attached on July 28, 2005, not only consistently refer to the 2004 NAS Report and fail to refer to the Belmont Report, but also require compliance with "stringent criteria," which is lacking in the Belmont Report. 151 Cong. Rec. H7019 (daily ed. July 28, 2005).

As Representative Norman Dicks stated in his introduction to the Conference Report, both the House and the Senate, in the conference report, wanted EPA to stop the use of humans during pesticide testing "until EPA develops regulations reflecting the recommendation of the National Academy of Science [sic] and follows the Nuremburg protocols." 151 Cong. Rec. at H7019; *see also* 151 Cong. Rec. at H7021 (Rep. Solis) (criticizing EPA's earlier proposed rule as "contrary to the recommendations of the NAS and the ethical guidelines of the Nuremburg Code that we require in this amendment"). This language tracks the language used in the 2004 NAS Report for its seventeen principles—that is, "recommendations,"

A129. This language also demonstrates that Congress wanted EPA to follow those proposals actually put forth by the NAS, rather than simply those that might have been referred to by the NAS in its 2004 Report.

III. The EPA Rule Is Inconsistent With The Nuremberg Code That Congress Adopted By Statute.

Congress required EPA to act consistently with the Nuremberg Code because that code reflects the importance of obtaining meaningful consent before any tests can be conducted on humans for non-therapeutic purposes. The Nuremberg Code was devised by American and foreign prosecutors in the aftermath of World War II in the face of the terrible extremes to which human experimentation had been taken in Germany at that time. It is a document grounded in fundamental principles of human rights, adopted by countries around the world and agencies within the United States as the appropriate basis for the responsible and respectful use of human subjects for the purposes of scientific experimentation.

And Congress has made it the law for EPA to follow in this case. Congress required EPA to promulgate "strict scientific and ethical requirements that are consistent with . . . the principles of the Nuremberg Code," to ensure scientific rigor and to prevent ethical abuses in intentional human dosing toxicity studies for pesticides. *See* § 201.

EPA failed to follow Congress's instruction. The first principle articulated in the Nuremberg Code states:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. . . .

A529.

The EPA's rule does not conform to the Nuremberg principle of voluntary consent because the EPA rule violates the standards of 1) individualized personal consent 2) informed consent and 3) voluntary consent.

Nor is this new. Senator Boxer noted that studies had in the past "routinely violate[d] ethical and scientific standards laid out in the Nuremberg Code." 151 Cong. Rec. at S7553 (statement of Sen. Boxer).

These violations prompted Congressional action. Congress' goal was to stop EPA from relying on studies that lacked fundamentally fair consent. As Representative Solis explained, Section 201 was designed to ensure that "EPA may not consider or rely on any intentional human-dosing study that does not meet the minimum ethical and scientific criteria recommended by

the Nuremberg Code."[4] 151 Cong. Rec. H7021, 7021 (daily ed. July 28, 2005) (statement of Rep. Solis).

Under the EPA rule, any "legally authorized representative" may give consent. 40 C.F.R. §§ 26.1116, 26.1117(a), (b)(1) & (b)(2). As defined by the EPA, a "legally authorized representative" is an "individual or judicial or other body authorized under applicable law to consent on the behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." 40 C.F.R. § 26.1102(c). By defining "legally authorized representative" under "applicable law," the meaning of "consent" varies depending on the site of experimentation – including sites in foreign countries that have not accepted American concepts of individual rights or the necessity of individual consent. Congress did not provide for consent by a representative and the Nuremberg Code expressly requires "[t]he voluntary consent of the human subject." EPA's rule violates the standard of

[4] As we observed in Part I of this brief, *supra*, sponsor statements "greatly aid in making the [statute's] purpose apparent." Max Radin, *A Short Way With Statutes*, 56 Harv. L. Rev. 388, 411 (1942); *see also Pub. Employees Ret. Sys. v. Betts*, 492 U.S. 158, 179 (1989) (giving weight to Senator Yarborough's views on the construction of the Age Discrimination in Employment Act because he was a sponsor); *Pacific Gas & Elec. Co. v. Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 220 n.23 (1983) (relying on a 1965 explanation by "an important figure in the drafting of the 1954 [Atomic Energy] Act"); *see, e.g., National Endowment for the Arts v. Finley*, 524 U.S. 569, 573-74 (1998) (sponsors' statements); *Conroy v. Aniskoff*, 507 U.S. 511, 516-17 & n. 12 (1993) (sponsors' statements).

individualized consent because it expressly allows "consent" to be given by an entity other than the human subject.

EPA's rule also fails to ensure that the human subject is appropriately informed of the risks presented by the research. The Nuremberg Code similarly explains, "before the acceptance of an affirmative decision by the experimental subject there should be made known to him … all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment." Contrarily, the EPA rule adopts old practices that have led to widespread misunderstanding about research risks among the subjects of that research. *See Human Pesticide Experiments* at 35-38 (finding that prior pesticide experiments on humans used such complex language in their consent forms that it is unlikely the volunteers understood the risks) (A703-05). The EPA's rule disseminates a pre-existing standard that has led to common violations of the Nuremberg Code's informed consent requirements.

EPA's rule similarly fails to ensure that human subjects who provide consent do so voluntarily. The Nuremberg Code demands that the human subject be "so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching,

or other ulterior form of constraint or coercion." Instead of adopting the Nuremberg's clear and absolute standard, EPA's rule provides for human studies to include undefined "additional safeguards" to protect "the rights and welfare" of subjects who "are likely to be vulnerable to coercion or undue influence." 40 C.F.R. § 26.1111. The indefinite standards allow total discretion to the conductors of the experiment.

There are significant deficiencies in the informed consent of the subjects tested in several of the experiments on which EPA has in the past relied, including the inadequate disclosure of potential harms, complex language, easily misunderstood consent forms, and plainly not obtaining consent.

Some experiments featured consent forms and accompanying information sheets that failed to explain or downplayed the health risks associated with the pesticide exposures involved in the experiments. *See Human Pesticide Experiments* at 35-38 (stating that the potential harms were not adequately disclosed Chloropicrin, Dimethoate, Amitraz (1998) and Amitraz (1992) studies) (A 703-05).

For example, consent forms in experiments involving dimethoate did not explain the relevant risks. The Dimethoate Experiment (2004), an organophosphate pesticide manufactured by BASF, utilized a consent form

that does not identify the test substance as a pesticide or describe potential health effects. *Human Pesticide Experiments* at 18 (A 686). Dimethoate had been identified by EPA as a suspected carcinogen, a developmental toxicant, and a neurotoxicant. Scorecard: the Pollution Information Site, *Chemical Profile: Dimethoate,* http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=60%2d51%2d5 (last visited Sept. 30, 2006). It is a suspected cardiovascular or blood toxicant, gastrointestinal or liver toxicant, kidney toxicant, and skin or sense organ toxicant. *Id*. The informed consent form used in the Dimethoate experiment did not identify any of these potential risks. *Human Pesticide Experiments* at 18 *(citing* W.J.A. Meuling and L. Roza, *Urinary Excretion Profile of Dimethoate and its Metabolites after Single Oral Administration of Dimethoate in Male Volunteers* (Dec. 28, 2004)) (A 686). Furthermore, the written information presented to test subjects states that "not a single health effect is expected" and characterizes the chemical as "used to protect or cure all kinds of plants, fruits and crops from disease." *Id.*

Even when risks are explained in the consent forms, the language is often so complex that participants do not understand the risks. *See Human Pesticide Experiments* at 35-38 (observing that three prior experiments used such complex language in their consent forms that it was unlikely the

volunteers understood to the risks) (A703-05). In a 1999 Phosmet study, an ethics committee identified "volunteer information [that] is difficult to understand," and recommended that "[s]ome effort should be made to simplify the volunteer information," although researchers declined to make any of these changes. *Id.* at 30 (quoting S. Freestone, S.J. Mair, & P. McFarlane, *A Randomised, Double Blind, Ascending Single Oral Dose Study with Phosmet to Determine the No Effect Level on Plasma and RBC Cholinesterase Activity* (June 4, 1999)) (A698).

Other studies have not even been able to establish that they ever obtained any kind of consent at all. A 1969 Dichlorvos experiment made no assertion of having obtained any informed consent, and congressional investigators were unable to obtain any evidence of consent from the principals behind 1997 Dichlorvos, 1996 Methyl Isothiocyanate, 1977 Ethephen, 1972 Ethrel, and 1971 Carbamates experiments. *Human Pesticide Experiments* at 35-38 (A703-05).

And of course, some terribly tragic cases of uninformed consent are not unknown to the federal government.[5] Nor are they unknown elsewhere.

[5] Consider the uninformed consent provided by the victims of the Tuskegee Syphilis Study, 400 of whom were permitted to suffer from the disease although the United States Public Health Service had a cure readily available for them. Experimenters continued this study even though a proven and 100% effective cure for syphilis had already been found. Barbara A. Noah,

EPA has documented troubling examples of English test subjects being dosed with the pesticide "Doom"[6] and Scottish subjects with orange juice laced with the insecticide Aldicarb.[7]

This rather sordid history of pesticide testing is particularly troubling because the Nuremberg Code has a long and distinguished history of

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The Participation of Underrepresented Minorities in Clinical Research, 29 Am. J. L. and Med. 221, 230 (2003) (describing how the Tuskegee studies continued some two decades after a cure for syphilis had become available). In some cases, researchers intervened to prevent treatment when other physicians diagnosed subjects as having syphilis. Predictably, many subjects died of syphilis during the study. *See generally Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study (*Susan M Reverby ed. 2000); Robert M. White, *Unraveling the Tuskegee Study of Untreated Syphilis,* 160 Archives of Internal Med. 585 (2000); Department of Health and Human Services: Center of Disease Control and Prevention, *The Tuskegee Timeline*, http://www.cdc.gov/nchstp/od/tuskegee/time.htm (last visited Sept. 28, 2006).

[6] *See* Molly Evans, *The English Patients: Human Experiments and Pesticide Policy*, The Environmental Working Group, July 1998, http://www.epa.gov/oscpmont/sap/meetings/1998/december/english.pdf (last visited Oct. 7, 2006) ("In three related studies conducted just last year for Amvac Chemical Corporation, headquartered in City of Commerce, California, for example, researchers at the Medeval Laboratories in Manchester, England dissolved a neurotoxic insecticide, dichlorvos, in corn oil and paid a small number of adult men to eat it in a test of the chemical's acute effects."). Dichlorvos is often marketed under the name "Doom." *Id.*

[7] *See id.* (documenting study commissioned by Rhone-Poulenc and conducted in 1992 on 38 men and 9 women at the Inveresk Clinical Laboratory in Scotland, "subjects were given a light breakfast on the day of the study, including a drink of orange juice" containing a placebo or various doses of aldicarb, an extremely toxic insecticide resulting in subject reports of "profuse sweating," "headaches," and "light-headedness").

protecting human subjects, as courts, agencies, and the international community have recognized.

The former have recognized that the code "is absolutely essential...to satisfy moral, ethical and legal concepts." *Washington v. Harper*, 494 U.S. 210, 238 (1990) (Steven, J., dissenting). The United States Military Tribunal that established the Nuremberg Code set a standard against which to judge German scientists who experimented with human subjects during the Holocaust. *See United States v. Stanley*, 483 U.S. 669, 687 (1987) (noting that the Nuremberg Code was created as uniform standard to govern scientists of permissible medical experiments in the Nuremberg Trials).[8] The code stands for the principle that "experimentation with unknowing

[8] The Nuremberg Code is the "most complete and authoritative statement of the law of informed consent to human experimentation." *Grimes v. Kennedy Krieger Institute, Inc*., 782 A.2d 807,835 (Md. 2001); *see also Whitlock v. Duke University* 637 F.Supp. 1463, 1470 (M.D.N.C.1986) (Nuremberg Code was adopted "as a proper statement of the law of informed consent in connection with the trials of German Scientists for human experimentation after World War II"); *Kaimowitz v. Michigan Dep't Mental Health*, No. 73 Civ. 19434-AW (Mich. Cir. Ct., Wayne County, July 10, 1973) (unreported), reprinted in A. Brooks, *Law, Psychiatry And The Mental Health System* 902 (1974) ("In the Nuremberg Judgment, the elements of what must guide us in decision are found. The involuntarily detained mental patient must have legal capacity to give consent. He must be so situated as to be able to exercise free power of choice without any element of force, fraud, deceit, duress, overreaching, or other ulterior form of restraint or coercion. He must have sufficient knowledge and comprehension of the subject matter to enable him to make an understanding decision. The decision must be a totally voluntary one on his part.").

human subjects is morally and legally unacceptable." *Id*. It "requires that the informed, voluntary, competent, and understanding consent of the research subject be obtained." *Grimes v. Kennedy Krieger Inst , Inc.*, 782 A.2d 807,835 (Md. 2001).

But EPA's rule fails to adhere to the code. Although, for example, the Code requires free choice by testing subjects "without the intervention of any element" of, among other things, "over-reaching, or other ulterior forms of constraint or coercion," A529, EPA's rule only requires that coercion be "minimized." The Nuremberg Code, and Congress's statute, is much more comprehensive.

Each and every principle of the Nuremberg Code, in short, has to be incorporated in the EPA rule in full, and the agency has failed to do so in the rule it has promulgated.

CONCLUSION

For the foregoing reasons amici members of Congress urge the court to vacate and remand the Human Testing Rule, 71 Fed. Reg. 6138-01 (Feb. 6, 2006), encoded at 40 C.F.R. Parts 9 and 26, to the agency for reconsideration.

Respectfully submitted,

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October 11, 2006

Certificate of Compliance with Rule 32(a)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 5,581 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2003 in a 14 point, Times New Roman font.

October 11, 2006

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Stanley N. Alpert

ANTI-VIRUS CERTIFICATION FORM
Pursuant to Second Circuit Local Rule 32(a)(1)(E)

CASE NAME: Natural Resources Defense Council v. United States Environmental Protection Agency

DOCKET NUMBER: 06-0820-ag, 06-1895-ag(con), 06-2149-ag(con), 06-2360-ag(con)

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Angela Huskey/DC/USEPA/US	To	"Wall, Michael", Jan Hasselman, Virginia Ruiz
	cc	"Greenberg, Alan (ENRD)"
07/29/2009 01:20 PM	bcc	
	Subject	Redline document -- FRE 408 Communication

Settlement Communication -- Subject to Fed. R. Evid. 408

Hi all,

As we discussed in our call on Monday, I'm attaching a redline document that tracks all of the changes that are being proposed from the current rule on human subjects.

Proposed changes from current rule for settlement negotiations (7-29-09).doc

Thanks,
Angela

****

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Confidential Settlement Communication Subject to FRE 408
Do Not Release

[Code of Federal Regulations]
[Title 40, Volume 1]
[Revised as of January 1, 2008]
From the U.S. Government Printing Office via GPO Access

TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY

PART 26: PROTECTION OF HUMAN SUBJECTS--Table of Contents

Subpart K: Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

§ 26.1101 To what does this subpart apply?

(a) Except as provided in paragraph (c~~b~~) of this section, subpart K of this part applies to all research initiated after [insert effective date of amended rule]~~April 7, 2006~~ involving intentional exposure of a human subject to a pesticide if, at any time prior to initiating such research, any person who conducted or supported such research intended either to~~:~~

~~(1) To~~ submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA or to~~the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a); or~~

~~(2) To~~ hold the results of the research for later inspection by EPA under any regulatory statute administered by EPA. This subpart does not apply to research with a test material that is a pesticide if the primary purpose of the research is to evaluate a property of a test material when it is used for non-pesticidal purposes. Examples include research to evaluate the efficacy of a test material as a human or animal drug~~the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or section 408 of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. 346a)~~.

(b) For purposes of determining a person's intent under paragraph (a), EPA may consider any available and relevant information. EPA shall rebuttably presume the existence of intent under the first sentence of paragraph (a) if:

(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA and, at the time the research was initiated, the results of such research would be relevant to EPA's exercise of its regulatory authority with respect to that class of people, products, or activities.

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(c) Unless otherwise required by the Administrator, research is exempt from this subpart if it involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from previously conducted studies, and if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(d~~e~~) The Administrator retains final judgment as to whether a particular activity ~~within the scope of paragraphs (a) and (b) of this section~~ is covered by this subpart.

(e~~d~~) Compliance with this subpart requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f~~e~~) This subpart does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects. Reference to State or local laws in this subpart is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(g~~f~~) This subpart does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

~~(g) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available information relevant to determining the intent of a person who conducts or supports research with human subjects after the effective date of the rule. EPA shall rebuttably presume such intent existed if:~~
~~(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or~~
~~(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA under FIFRA or the FFDCA and, at the time the research was initiated, the results of the research would be relevant to EPA's exercise of its authority under FIFRA or the FFDCA with respect to that class of people, products, or activities.~~

§ 26.1102 Definitions.

(a) ~~For purposes of this subpart,~~ ***Administrator*** means the Administrator of the Environmental Protection Agency (EPA) and any other officer or employee of EPA to whom authority has been delegated.

(b) ***Institution*** means any public or private entity or agency (including Federal, State, and other agencies).

(c) *Initiation* of research involving human subjects is considered to occur as of the enrollment of the first subject in the research.
~~(c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.~~

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(d) *Research* means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this subpart, whether or not they are considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

(3) "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(f) *IRB* means an institutional review board established in accord with and for the purposes expressed in this part.

(g) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(h) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(i) *Research involving intentional exposure of a human subject* means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

(j) *Person* means any person, as that term is defined in FIFRA section 2(s) (7 U.S.C. 136), except:

(1) A federal agency that is subject to the provisions of the Federal Policy for the Protection of Human Subjects of Research, and

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(2) A person when performing human research supported by a federal agency covered by paragraph (j)(1) of this section.

(k) *Pesticide* means any substance or mixture of substances meeting the definition in 7 U.S.C. 136(u) [Federal Insecticide, Fungicide and Rodenticide Act sec. 2(u)] and any other substance or mixture of substances that is an ingredient in a pesticide or a degradate or metabolite of an ingredient of a pesticide.

§§ 26.1103-26.1106 [Reserved]

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§ 26.1107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities which are presented for its approval. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as prisoners or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 26.1108 IRB functions and operations.

In order to fulfill the requirements of this subpart each IRB shall:

(a) Follow written procedures:

(1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

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(2) For determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;

(3) For ensuring prompt reporting to the IRB of proposed changes in research activity; and

(4) For ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Environmental Protection Agency of:

(1) Any unanticipated problems involving risks to human subjects or others;

(2) Any instance of serious or continuing noncompliance with this subpart of the requirements or determinations of the IRB; or

(3) Any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used (see Sec. 26.1110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 26.1109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this subpart.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec. 26.1116. The IRB may require that information, in addition to that specifically mentioned in Sec. 26.1116 be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with Sec. 26.1117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

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(e) An IRB shall conduct continuing review of research covered by this subpart at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§ 26.1110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) (1) An IRB may use the expedited review procedure to review either or both of the following:

(i) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(ii) Minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Sec. 26.1108(c~~b~~).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Administrator may restrict, suspend, or terminate, an institution's or IRB's use of the expedited review procedure for research covered by this subpart.

§ 26.1111 Criteria for IRB approval of research.

(a) In order to approve research covered by this subpart the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

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(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject ~~or the subject's legally authorized representative~~, in accordance with, and to the extent required by Sec. 26.1116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by Sec. 26.1117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 26.1112 Review by institution.

Research covered by this subpart that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

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§ 26.1113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Administrator of EPA.

§ 26.1114 Cooperative research.

In complying with this subpart, sponsors, investigators, or institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 26.1115 IRB records.

(a) An IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB in the same detail as described in Sec. 26.1108(a) and Sec. 26.1108(b).

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(7) Statements of significant new findings provided to subjects, as required by Sec. 26.1116(b)(5).

(b) The records required by this subpart shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of EPA at reasonable times and in a reasonable manner.

§ 26.1116 General requirements for informed consent.

No investigator may involve a human being as a subject in research covered by this subpart unless the investigator has obtained the legally effective informed consent of the subject ~~or the subject's legally authorized representative~~. An investigator shall seek such consent only under circumstances that provide the prospective subject ~~or the representative~~ sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject ~~or the representative~~ shall be in language understandable to the subject ~~or the representative~~. No informed consent, whether oral or written, may include any exculpatory language through which the subject ~~or the representative~~ is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. In seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

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(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in this subpart are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(d) Nothing in this subpart is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(e) The ~~If the research involves intentional exposure of subjects to a pesticide, the~~ subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.

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§ 26.1117 Documentation of informed consent.

(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject ~~or the subject's legally authorized representative~~. A copy shall be given to the subject~~person signing the form~~.

(b) The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by Sec. 26.1116. This form may be read to the subject ~~or the subject's legally authorized representative~~, but in any event, the investigator shall give ~~either~~ the subject ~~or the representative~~ adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by Sec. 26.1116 have been presented orally to the subject ~~or the subject's legally authorized representative~~. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject ~~or the representative~~. Only the short form itself is to be signed by the subject ~~or the representative~~. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject ~~or the representative~~, in addition to a copy of the short form.

§§ 26.1118-26.1122 [Reserved]

§ 26.1123 Early termination of research.

The Administrator may require that any project covered by this subpart be terminated or suspended when the Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.

§ 26.1124 [Reserved]

§ 26.1125 Prior submission of proposed human research for EPA review.

Any person or institution who intends to conduct or sponsor human research covered by Sec. 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by Sec. 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

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(1) The potential risks to human subjects;

(2) The measures proposed to minimize risks to the human subjects;
(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and

(5) The balance of risks and benefits of the proposed research.

(b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.

(c) Information about how subjects will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.

Subpart L: Prohibition of Third-Party Research ~~for Pesticides~~ Involving Intentional Exposure of Human Subjects to a Pesticide who are Children or Pregnant or Nursing Women

§ 26.1201 To what does this subpart apply?

Subpart L applies to any ~~person who, after April 7, 2006, conducts or supports~~ research ~~with a human~~ subject to subpart K of this part. ~~intended:~~

~~(1) For submission to EPA for consideration in connection with any action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a); or~~

~~(2) To be held for later inspection by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or section 408 of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. 346a).~~

~~(b) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available information relevant to determining the intent of a person who conducts or supports research with human subjects after the effective date of the rule. EPA shall rebuttably presume such intent existed if:~~

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~~(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or~~

~~(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA under FIFRA or the FFDCA and, at the time the research was initiated, the results of the research would be relevant to EPA's exercise of its authority under FIFRA or the FFDCA with respect to that class of people, products, or activities.~~

§ 26.1202 Definitions.

The definitions in Sec. 26.1102 apply~~shall be applicable~~ to this subpart as well. In addition, the definitions at 45 CFR 46.202(a) through (f) and at 45 CFR 46.202(h) apply~~are applicable~~ to this subpart. In addition, a *child* is a person who has not attained the age of 18 years.

§ 26.1203 Prohibition of research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child to a pesticide.

Notwithstanding any other provision of this part, under no circumstances shall a person conduct or support research covered by Sec. 26.1201 that involves intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child to a pesticide.

Subpart M: Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits to EPA a report containing the results of any human research on or with a pesticide if:

(a) The report is submitted after [insert effective date of amended rule]~~April 7, 2006~~, and

(b) The report is submitted for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA~~the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a)~~.

§ 26.1302 Definitions.

The definitions in sec.~~See.~~ 26.1102~~102 shall~~ apply to this subpart as well.

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§ 26.1303 Submission of information pertaining to ethical conduct of completed human research.

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

(a) Copies of all of the records relevant to the research specified by Sec. 26.1115(a) to be prepared and maintained by an IRB.

(b) Copies of all of the records relevant to the information identified in Sec. 26.1125(a) through (f).

(c) Copies of sample records used to document informed consent as specified by Sec. 26.1117, but not identifying any subjects of the research.

(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.

Subpart N [Reserved]

Subpart O: Administrative Actions for Noncompliance

§ 26.1501 To what does this subpart apply?

This subpart applies to any human research subject to subparts A through L of this part. References to State or local laws in this subpart are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

§ 26.1502 Lesser administrative actions.

(a) If apparent noncompliance with the applicable regulations in subparts A through L of this part concerning the operation of an IRB is observed by an officer or employee of EPA or of any State duly designated by the Administrator during an inspection. EPA may send a letter describing the noncompliance to the IRB and to the parent institution. EPA~~The agency~~ will require that the IRB or the parent institution respond to this letter within a reasonable time period specified by EPA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

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(b) On the basis of the IRB's or the institution's response, EPA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, EPA~~the Agency~~ may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and EPA will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, EPA may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

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§ 26.1503 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by EPA ~~the Agency~~ under Sec. 26.1502(a) and the ~~EPA~~ Administrator determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Administrator may institute appropriate proceedings.

(b) The Administrator may disqualify an IRB or the parent institution from studies subject to this part if the Administrator determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects of research.

(c) If the Administrator determines that disqualification is appropriate, the Administrator will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing human research, covered by subparts A through L of this part, conducted under the review of the IRB. EPA will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and investigators, may also be sent a notice of the disqualification. In addition, EPA~~the agency~~ may elect to publish a notice of its action in the Federal Register.

(d) EPA may refuse to consider in support of a regulatory decision the data from human research, covered by subparts A through L of this part, that was reviewed by an IRB or conducted at an institution during the period of disqualification, unless the IRB or the parent institution is reinstated as provided in Sec. 26.1505, or unless such research is deemed scientifically sound and crucial to the protection of public health, under the procedure defined in Sec. 26.1706.

§ 26.1504 Public disclosure of information regarding revocation.

A determination that EPA has disqualified an institution from studies subject to this part and the administrative record regarding that determination are discloseable~~disclosable~~ to the public under 40 CFR part 2.

§ 26.1505 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated to conduct studies subject to this part if the Administrator determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB has taken or plans to take, that the

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IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under Sec. 26.1502(b)(4~~e~~).

§ 26.1506 Debarment.

If EPA determines that an institution or investigator repeatedly has not complied with or has committed an egregious violation of the applicable regulations in subparts A through L of this part, EPA may recommend that institution or investigator be declared ineligible to participate in EPA-supported research (debarment). Debarment will be initiated in accordance with procedures specified at 2 CFR part 1532.

§ 26.1507 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other statutorily authorized proceedings or actions. EPA may, at any time, on its own initiative or through the Department of Justice, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. EPA~~The Agency~~ may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

Subpart P: Review of Proposed and Completed Human Research

§ 26.1601 To what does this subpart apply?

This subpart applies to both of the following:

(a) Reviews by EPA and by the Human Studies Review Board of proposals to conduct new research subject to 40 CFR 26.1125, and

(b) Reviews by EPA after [insert effective date of the revised rule] and, to the extent required by sec. 26.1604, by the Human Studies Review Board of reports of completed research subject to 40 CFR 26.1701.

§ 26.1602 Definitions.

The definitions in sec. 26.1102 apply to this subpart as well.

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§ 26.1603 EPA review of proposed human research.

(a) EPA shall review all proposals for new human research~~protocols~~ submitted under Sec. 26.1125 of this part in a timely manner.

(b) In reviewing proposals for new human research covered by subpart K, the Administrator shall consider and make determinations regarding the proposed research, including:

(1) Whether the research would be likely to produce data that address an important scientific or policy question that cannot be resolved on the basis of animal data or human observational research;

(2) Whether the proposed research is designed in accordance with current scientific standards and practices to:

(i) Address the research question;

(ii) Include representative study populations for the endpoint in question; and

(iii) Have adequate statistical power to detect appropriate effects.

(3) Whether the investigator proposes to conduct the research in accordance with recognized good research practices, including, when appropriate, good clinical practice guidelines and monitoring for the safety of subjects.

(c) In reviewing proposals for new research covered by subpart K, the Administrator shall consider and make determinations regarding ethical aspects of the proposed research including:

(1) Whether adequate information is available from prior animal studies or from other sources to assess the potential risks to subjects in the proposed research;

(2) Whether the research proposal adequately identifies anticipated risks to human subjects and their likelihood of occurrence, minimizes identified risks to human subjects, and identifies likely benefits of the research and their distribution.

(3) Whether the proposed research presents an acceptable balance of risks and benefits. In making this determination for research intended to reduce the interspecies uncertainty factor in a pesticide risk assessment, the Administrator shall consider Recommendation 4-1 of the National Research Council as contained in its report entitled Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues (2004).

(4) Whether subject selection will be equitable;

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(5) Whether subjects' participation would follow free and fully informed consent;

(6) Whether an appropriately constituted Institutional Review Board or its foreign equivalent has approved the proposed research;

(7) If any person from a vulnerable population may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate;

(8) If any person with a condition that would put them at increased risk for adverse effects may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate;

(9) Whether any proposed payments to subjects are consistent with the principles of justice and respect for persons, and whether they are so high as to constitute undue inducement or so low as to be attractive only to individuals who are socioeconomically disadvantaged; and

(10) Whether the sponsor or investigator would provide needed medical care for injuries incurred in the proposed research, without cost to the human subjects.

(d) With respect to any research or any class of research, the Administrator may recommend additional conditions which, in the judgment of the Administrator, are necessary for the protection of human subjects.

(e~~(b)~~) In reviewing proposals covered by this section~~subpart~~, the Administrator may take into account factors such as whether the submitter ~~applicant~~ has been subject to a termination or suspension under Sec. 26.123(a) or Sec. 26.1123 and whether the submitter~~applicant~~ or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Administrator, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

(f~~e~~) When research covered by subpart K takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in subpart K. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration of Helsinki, issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if the Administrator determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in subpart K, the Administrator may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in subpart K.

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(gd) Following initial evaluation of the protocol ~~by Agency staff~~, EPA shall submit the protocol and all supporting materials, together with the staff evaluation, to the Human Studies Review Board.

(he) EPA shall provide~~notify~~ the submitter of the proposal copies~~of the results~~ of the EPA and Human Studies Review Board reviews.

§ 26.16041602 EPA review of completed human research.

(a) When considering, ~~data~~ under any regulatory statute it administers, data from completed ~~FIFRA or FFDCA from~~ research involving intentional exposure of humans to a pesticide, EPA shall thoroughly review the material submitted under Sec. 26.1303, if any, and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

(b) EPA shall submit its review of data from human research covered by subpart Q, together with the available supporting materials, to the Human Studies Review Board if EPA decides to rely on the data and:

(1) The data are derived from research initiated after April 7, 2006, or

(2) The data are derived from research initiated before April 7, 2006, and the research was conducted for the purpose of identifying or measuring a toxic effect.

(c) In its discretion, EPA may submit data from research not covered by paragraph (b) of this section to the Human Studies Review Board for their review.

(d) EPA shall provide~~notify~~ the submitter of the research copies~~of the results~~ of the EPA and Human Studies Review Board reviews.

§ 26.16051603 Operation of the Human Studies Review Board.

EPA shall establish and operate a Human Studies Review Board as follows:

(a) Membership. The Human Studies Review Board shall consist of members who are not employed by EPA, who meet the ethics and other requirements for special government employees, and who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology.

(b) Responsibilities. The Human Studies Review Board shall comment on the scientific and ethical aspects of research proposals and reports of completed research with human subjects submitted by EPA for its review and, on request, advise EPA on ways to strengthen its programs for protection of human subjects of research.

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§ 26.1606 Human Studies Review Board review of proposed human research.

In commenting on proposals for new research submitted to it by EPA, the Human Studies Review Board shall consider the scientific merits and ethical aspects of the proposed research, including all elements listed in section 26.1603(b) and (c) and any additional conditions recommended pursuant to sec. 26.1603(d).

§ 26.1607 Human Studies Review Board review of completed human research.

In commenting on reports of completed research submitted to it by EPA, the Human Studies Review Board shall consider the scientific merits and ethical aspects of the completed research, and shall apply the appropriate standards in Subpart Q.

Subpart Q: Ethical Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

§ 26.1701 To what does this subpart apply?

This subpart applies to EPA's decisions whether to rely, in ~~its~~ actions taken under any regulatory statute it administers, ~~the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a)~~ on scientifically valid and relevant data from research involving intentional exposure of human subjects to a pesticide.

§ 26.1702 Definitions.

The definitions in Sec. 26.1102 and Sec. 26.1202 shall apply to this subpart as well.

§ 26.1703 Prohibitions

(a) Prohibition of reliance on scientifically invalid research involving intentional exposure of a human subject to a pesticide ~~human subjects who are pregnant women (and therefore their fetuses), nursing women, or children~~.

EPA shall not rely on data from research involving intentional exposure of a human subject to a pesticide unless EPA determines that the data are relevant to a scientific or policy question important for EPA decision-making, that the data were derived in a manner that makes them scientifically reliable, and that it is appropriate to use the data for the purpose proposed by EPA. In making such determinations, EPA shall consider:

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(1) Whether the research was designed and conducted in accordance with appropriate scientific standards and practices prevailing at the time the research was conducted;

(2) The extent to which the research subjects are representative of the populations for the endpoint or endpoints in question; and

(3) The statistical power of the data to support the scientific conclusion EPA intends to draw from the data

(4) In a study that reports only a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), whether a dose level in the study gave rise to a biological effect, thereby demonstrating that the study had adequate sensitivity to detect an effect of interest.

(b) Prohibition of reliance on research involving intentional exposure to a pesticide of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children.

Except as provided in Sec. 26.1706, ~~in actions within the scope of Sec. 26.1701~~ EPA shall not rely on data from any research involving intentional exposure to a pesticide of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults not covered by section 26.1705~~conducted before April 7, 2006~~.

(a) This section applies to decisions covered by section 26.1701 that are not covered by section 26.1705.

(b) Except as provided in Sec. 26.1706, ~~in actions within the scope of Sec. 26.1701,~~ EPA shall not rely on data from any research involving intentional exposure of any human subject to a pesticide, where that research was not covered by subparts A through L~~initiated before April 7, 2006~~, if there is clear and convincing evidence that the conduct of the research was fundamentally unethical (e.g., the research was intended to seriously harm participants or failed to obtain informed consent), or was ~~significantly~~ deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. This prohibition is in addition to the prohibitions in Sec. 26.1703.

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults initiated ~~conducted~~ after April 7, 2006, and subject to subparts A through L or another codification of the Common Rule.

(a) This section applies to decisions covered by section 26.1701, if the research on which EPA intends to rely meets both of the following conditions:

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(1) the research was initiated after April 7, 2006.

(2) the research was subject, at the time the research was conducted, either to subparts A through L of this part or to another codification of the Basic Policy for the Protection of Subjects in Human Research Conducted or Supported by a Federal Agency (generally referred to as the "Common Rule").

(b) Except as provided in Sec. 26.1706, ~~in actions within the scope of Sec. 26.1701,~~ EPA shall not rely on data from any research ~~initiated after April 7, 2006~~, unless EPA determines ~~has adequate information to determine~~ that the research was conducted in substantial compliance with one of the following:

(1) all applicable provisions of subparts A through L of this part~~,~~ or another codification of the Common Rule, whichever is applicable.

(2) ~~if conducted in a foreign country,~~ under procedures at least as protective of subjects as those in subparts A through L of this part or another codification of the Common Rule, whichever is applicable, if the research was conducted in a foreign country.

(c) Except as provided in Sec. 26.1706, EPA shall not rely on data from any research, unless EPA determines that the research was conducted in substantial compliance with one fo the following:

(1) a proposal that was found to be acceptable under Sec. 26.1603(c), and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impair their informed consent. If EPA discovers that the submitter of the proposal materially misrepresented or knowingly omitted information that would have altered the outcome of EPA's evaluation of the proposal under Sec. 26.1603(c), EPA shall not rely on that data.

(2) a proposal that would have been found to be acceptable under Sec. 26.1603(c), if it had been subject to review under that section, and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impair their informed consent.

~~(a)~~(d) ~~–~~This prohibition is in addition to the prohibitions in Sec. 26.1703.

§ 26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

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This section establishes the exclusive criteria and procedure by which EPA may decide to rely on data from research that is not acceptable under the standards in §§ 26.1703 through 26.1705. EPA may rely on such data only if all the conditions in paragraphs (a) through (d) of this section are satisfied:

(a) EPA has obtained the views of the Human Studies Review Board concerning the proposal to rely on the otherwise unacceptable data,

(b) EPA has provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data,

(c) EPA has determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health, such as a limitation on the use of a pesticide, than could be justified without relying on the data, and

(d) EPA publishes a full explanation of its decision to rely on the otherwise unacceptable data, including a thorough discussion of the scientific and ethical deficiencies of the underlying research and the full rationale for finding that the standard in paragraph (c) of this section was met.

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Angela Huskey/DC/USEPA/US	To	"Wall, Michael"
	cc	"Greenberg, Alan (ENRD)"
05/27/2009 02:00 PM	bcc	
	Subject	RE: NRDC v EPA (human research rule)

Michael,

I've attached a clean version of the document that was sent to you on 5-20-09. It incorporates the changes that EPA was proposing.

Proposed regulatory changes for settlement discussions (clean).doc

Angela

****

Angela M.D. Huskey
Office of General Counsel, Pesticides and Toxic Substances Law Office
Mail Code 2333A
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Room 7426HH - Ariel Rios North
Phone: (202) 564-2892
Fax: (202) 564-5644

"Wall, Michael" Alan: Would you mind sending me a W... 05/27/2009 11:42:25 AM

From:	"Wall, Michael" <mwall@nrdc.org>
To:	"Greenberg, Alan (ENRD)" <Alan.Greenberg@usdoj.gov>
Cc:	Angela Huskey/DC/USEPA/US@EPA
Date:	05/27/2009 11:42 AM
Subject:	RE: NRDC v EPA (human research rule)

Alan:

Would you mind sending me a Word version of EPA's proposed changes to the regulatory language?

Michael

-----Original Message-----
From: Greenberg, Alan (ENRD) [mailto:Alan.Greenberg@usdoj.gov]
Sent: Wednesday, May 20, 2009 2:57 PM
To: Wall, Michael; Colangelo, Aaron; jhasselman@earthjustice.org; vruiz@farmworkerjustice.org
Cc: Huskey.Angela@epamail.epa.gov
Subject: NRDC v EPA (human research rule)

CONFIDENTIAL SETTLEMENT COMMUNICATION - FRE 408

Counsel:

I have attached two documents that EPA has prepared for the settlement discussions tomorrow. One contains proposed changes to regulatory language. The second lays out the key features of EPA's proposal.

We look forward to discussing these with you tomorrow afternoon.

Alan

[Code of Federal Regulations]
[Title 40, Volume 1]
[Revised as of January 1, 2008]
From the U.S. Government Printing Office via GPO Access

TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY

PART 26: PROTECTION OF HUMAN SUBJECTS--Table of Contents

Subpart K: Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

§ 26.1101 To what does this subpart apply?

(a) Except as provided in paragraph (c) of this section, subpart K of this part applies to all research initiated after [insert effective date of amended rule] involving intentional exposure of a human subject to a pesticide if, at any time prior to initiating such research, any person who conducted or supported such research intended either to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA or to hold the results of the research for later inspection by EPA under any regulatory statute administered by EPA. This subpart does not apply to research with a test material that is a pesticide if the primary purpose of the research is to evaluate a property of a test material when it is used for non-pesticidal purposes. Examples include research to evaluate the efficacy of a test material as a human or animal drug.

(b) For purposes of determining a person's intent under paragraph (a), EPA may consider any available and relevant information. EPA shall rebuttably presume such intent existed if:

(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA and, at the time the research was initiated, the results of such research would be relevant to EPA's exercise of its regulatory authority with respect to that class of people, products, or activities.

(c) Unless otherwise required by the Administrator, research is exempt from this subpart if it involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from previously conducted studies, and if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(d) The Administrator retains final judgment as to whether a particular activity is covered by this subpart.

(e) Compliance with this subpart requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This subpart does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects. Reference to State or local laws in this subpart is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(g) This subpart does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

§ 26.1102 Definitions.

(a) *Administrator* means the Administrator of the Environmental Protection Agency (EPA) and any other officer or employee of EPA to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including Federal, State, and other agencies).

(c) *Initiation* of research involving human subjects is considered to occur as of the enrollment of the first subject in the research.

(d) *Research* means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this subpart, whether or not they are considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

(3) "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably

expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(f) *IRB* means an institutional review board established in accord with and for the purposes expressed in this part.

(g) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(h) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(i) *Research involving intentional exposure of a human subject* means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

(j) *Person* means any person, as that term is defined in FIFRA section 2(s) (7 U.S.C. 136), except:

(1) A federal agency that is subject to the provisions of the Federal Policy for the Protection of Human Subjects of Research, and

(2) A person when performing human research supported by a federal agency covered by paragraph (j)(1) of this section.

(k) *Pesticide* means any substance or mixture of substances meeting the definition in 7 U.S.C. 136(u) [Federal Insecticide, Fungicide and Rodenticide Act sec. 2(u)] and any other substance or mixture of substances that is an ingredient in a pesticide or a degradate or metabolite of an ingredient of a pesticide.

§§ 26.1103-26.1106 [Reserved]

§ 26.1107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities which are presented for its approval. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as prisoners or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 26.1108 IRB functions and operations.

In order to fulfill the requirements of this subpart each IRB shall:

(a) Follow written procedures:

(1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(2) For determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;

(3) For ensuring prompt reporting to the IRB of proposed changes in research activity; and

(4) For ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Environmental Protection Agency of:

(1) Any unanticipated problems involving risks to human subjects or others;

(2) Any instance of serious or continuing noncompliance with this subpart of the requirements or determinations of the IRB; or

(3) Any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used (see Sec. 26.1110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 26.1109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this subpart.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec. 26.1116. The IRB may require that information, in addition to that specifically mentioned in Sec. 26.1116 be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with Sec. 26.1117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this subpart at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§ 26.1110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) (1) An IRB may use the expedited review procedure to review either or both of the following:

(i) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(ii) Minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Sec. 26.1108(c).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Administrator may restrict, suspend, or terminate, an institution's or IRB's use of the expedited review procedure for research covered by this subpart.

§ 26.1111 Criteria for IRB approval of research.

(a) In order to approve research covered by this subpart the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject, in accordance with, and to the extent required by Sec. 26.1116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by Sec. 26.1117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 26.1112 Review by institution.

Research covered by this subpart that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 26.1113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Administrator of EPA.

§ 26.1114 Cooperative research.

In complying with this subpart, sponsors, investigators, or institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 26.1115 IRB records.

(a) An IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB in the same detail as described in Sec. 26.1108(a) and Sec. 26.1108(b).

(7) Statements of significant new findings provided to subjects, as required by Sec. 26.1116(b)(5).

(b) The records required by this subpart shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of EPA at reasonable times and in a reasonable manner.

§ 26.1116 General requirements for informed consent.

No investigator may involve a human being as a subject in research covered by this subpart unless the investigator has obtained the legally effective informed consent of the subject. An investigator shall seek such consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject shall be in language understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. In seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in this subpart are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(d) Nothing in this subpart is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(e) The subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.

§ 26.1117 Documentation of informed consent.

(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject. A copy shall be given to the subject.

(b) The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by Sec. 26.1116. This form may be read to the subject, but in any event, the investigator shall give the subject adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by Sec. 26.1116 have been presented orally to the subject. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject. Only the short form itself is to be signed by the subject. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject, in addition to a copy of the short form.

§§ 26.1118-26.1122 [Reserved]

§ 26.1123 Early termination of research.

The Administrator may require that any project covered by this subpart be terminated or suspended when the Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.

§ 26.1124 [Reserved]

§ 26.1125 Prior submission of proposed human research for EPA review.

Any person or institution who intends to conduct or sponsor human research covered by Sec. 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by Sec. 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

(1) The potential risks to human subjects;

(2) The measures proposed to minimize risks to the human subjects;

(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and

(5) The balance of risks and benefits of the proposed research.

(b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.

(c) Information about how subjects will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.

Subpart L: Prohibition of Third-Party Research Involving Intentional Exposure of Human Subjects to a Pesticide who are Children or Pregnant or Nursing Women

§ 26.1201 To what does this subpart apply?

(a) Subpart L applies to any research subject to subpart K of this part.

(b) This subpart does not apply to research with a test material that is a pesticide if the primary purpose of the research is to evaluate a property of a test material when it is used for non-pesticidal purposes. Examples include research to evaluate the efficacy of a test material as a human or animal drug.

§ 26.1202 Definitions.

The definitions in Sec. 26.1102 apply to this subpart as well. In addition, the definitions at 45 CFR 46.202(a) through (f) and at 45 CFR 46.202(h) apply to this subpart. In addition, a *child* is a person who has not attained the age of 18 years.

§ 26.1203 Prohibition of research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child to a pesticide.

Notwithstanding any other provision of this part, under no circumstances shall a person conduct or support research covered by Sec. 26.1201 that involves intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child to a pesticide.

Subpart M: Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits to EPA a report containing the results of any completed human research on or with a pesticide if:

(a) The report is submitted after [insert effective date of amended rule], and

(b) The report is submitted for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA.

§ 26.1302 Definitions.

The definitions in sec. 26.1102 apply to this subpart as well.

§ 26.1303 Submission of information pertaining to ethical conduct of completed human research.

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

(a) Copies of all of the records relevant to the research specified by Sec. 26.1115(a) to be prepared and maintained by an IRB.

(b) Copies of all of the records relevant to the information identified in Sec. 26.1125(a) through (f).

(c) Copies of sample records used to document informed consent as specified by Sec. 26.1117, but not identifying any subjects of the research.

(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.

Subpart N [Reserved]

Subpart O: Administrative Actions for Noncompliance

§ 26.1501 To what does this subpart apply?

This subpart applies to any human research subject to subparts A through L of this part. References to State or local laws in this subpart are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

§ 26.1502 Lesser administrative actions.

(a) If apparent noncompliance with the applicable regulations in subparts A through L of this part concerning the operation of an IRB is observed by an officer or employee of EPA or of any State duly designated by the Administrator during an inspection. EPA may send a letter describing the noncompliance to the IRB and to the parent institution. EPA will require that the IRB or the parent institution respond to this letter within a reasonable time period specified by EPA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, EPA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, EPA may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and EPA will ordinarily direct any administrative action under this subpart against the institution.

However, depending on the evidence of responsibility for deficiencies, determined during the investigation, EPA may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§ 26.1503 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by EPA under Sec. 26.1502(a) and the Administrator determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Administrator may institute appropriate proceedings.

(b) The Administrator may disqualify an IRB or the parent institution from studies subject to this part if the Administrator determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects of research.

(c) If the Administrator determines that disqualification is appropriate, the Administrator will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing human research, covered by subparts A through L of this part, conducted under the review of the IRB. EPA will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and investigators, may also be sent a notice of the disqualification. In addition, EPA may elect to publish a notice of its action in the Federal Register.

(d) EPA may refuse to consider in support of a regulatory decision the data from human research, covered by subparts A through L of this part, that was reviewed by an IRB or conducted at an institution during the period of disqualification, unless the IRB or the parent institution is reinstated as provided in Sec. 26.1505, or unless such research is deemed scientifically sound and crucial to the protection of public health, under the procedure defined in Sec. 26.1706.

§ 26.1504 Public disclosure of information regarding revocation.

A determination that EPA has disqualified an institution from studies subject to this part and the administrative record regarding that determination are discloseable to the public under 40 CFR part 2.

§ 26.1505 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated to conduct studies subject to this part if the Administrator determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB has taken or plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the

standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under Sec. 26.1502(b)(4).

§ 26.1506 Debarment.

If EPA determines that an institution or investigator repeatedly has not complied with or has committed an egregious violation of the applicable regulations in subparts A through L of this part, EPA may recommend that institution or investigator be declared ineligible to participate in EPA-supported research (debarment). Debarment will be initiated in accordance with procedures specified at 2 CFR part 1532.

§ 26.1507 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other statutorily authorized proceedings or actions. EPA may, at any time, on its own initiative or through the Department of Justice, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. EPA may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

Subpart P: Review of Proposed and Completed Human Research

§ 26.1601 To what does this subpart apply?

This subpart applies to both of the following:

(a) Reviews by EPA and by the Human Studies Review Board of proposals to conduct new research subject to 40 CFR 26.1125, and

(b) Reviews by EPA after [insert effective date of the revised rule] and, to the extent required by sec. 26.1604, by the Human Studies Review Board of reports of completed research subject to 40 CFR 26.1701.

§ 26.1602 Definitions.

The definitions in sec. 26.1102 apply to this subpart as well.

§ 26.1603 EPA review of proposed human research.

(a) EPA shall review all proposals for new human research submitted under Sec. 26.1125 of this part in a timely manner.

(b) In reviewing proposals for new human research covered by subpart K, the Administrator shall consider and make determinations regarding the proposed research, including:

(1) Whether the research would be likely to produce data that address an important scientific or policy question that cannot be resolved on the basis of animal data or human observational research;

(2) Whether the proposed research is designed in accordance with current scientific standards and practices to:

(i) Address the research question;

(ii) Include representative study populations for the endpoint in question; and

(iii) Have adequate statistical power to detect appropriate effects.

(3) Whether the investigator proposes to conduct the research in accordance with recognized good research practices, including, when appropriate, good clinical practice guidelines and monitoring for the safety of subjects.

(c) In reviewing proposals for new research covered by subpart K, the Administrator shall consider and make determinations regarding ethical aspects of the proposed research including:

(1) Whether adequate information is available from prior animal studies or from other sources to assess the potential risks to subjects in the proposed research;

(2) Whether the research proposal adequately identifies anticipated risks to human subjects and their likelihood of occurrence, minimizes identified risks to human subjects, and identifies likely benefits of the research and their distribution.

(3) Whether the proposed research presents an acceptable balance of risks and benefits. In making this determination the Administrator shall apply the following:

(i) Research intended to reduce the interspecies uncertainty factor in a pesticide risk assessment presents an acceptable balance of risks and benefits only if human subjects' exposure to the pesticide can be reliably anticipated to pose no identifiable risk or a reasonable certainty of no harm to study participants, and only if it is designed and conducted in a manner likely to improve the scientific accuracy of EPA's extrapolation from animal to human data. Studies in which the observable changes serve as indicators or biomarkers of exposure, but are immediately reversible

upon cessation of exposure and would be expected to have no consequence to the health of the individual experiencing them, fall in the category of research posing a reasonable certainty of no harm to participants. Examples include changes in cholinesterase activity in blood which would be rapidly reversible and at low exposure would not be associated with any adverse effect, and detectable but clinically insignificant changes in blood pressure or heart rate in normotensive individuals.

(ii) Research intended to provide a clear health or environmental benefit to the community presents an acceptable balance of risks and benefits only if it can be reliably anticipated to cause no lasting harm to study human subjects.

(4) Whether subject selection will be equitable;

(5) Whether subjects' participation would follow free and fully informed consent;

(6) Whether an appropriately constituted Institutional Review Board or its foreign equivalent has approved the proposed research;

(7) If any person from a vulnerable population may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate;

(8) If any person with a condition that would put them at increased risk for adverse effects may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate;

(9) Whether any proposed payments to subjects are consistent with the principles of justice and respect for persons, and whether they are so high as to constitute undue inducement or so low as to be attractive only to individuals who are socioeconomically disadvantaged; and

(10) Whether the sponsor or investigator would provide needed medical care for injuries incurred in the proposed research, without cost to the human subjects.

(d) With respect to any research or any class of research, the Administrator may recommend additional conditions which, in the judgment of the Administrator, are necessary for the protection of human subjects.

(e) In reviewing proposals covered by this section, the Administrator may take into account factors such as whether the submitter has been subject to a termination or suspension under Sec. 26.123(a) or Sec. 26.1123 and whether the submitter or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Administrator, materially failed to discharge responsibility for the

protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

(f) When research covered by subpart K takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in subpart K. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration of Helsinki, issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if the Administrator determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in subpart K, the Administrator may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in subpart K.

(g) Following initial evaluation of the protocol, EPA shall submit the protocol and all supporting materials, together with the staff evaluation, to the Human Studies Review Board.

(h) EPA shall provide the submitter of the proposal copies of the EPA and Human Studies Review Board reviews.

§ 26.1604 EPA review of completed human research.

(a) When considering, under any regulatory statute it administers, data from completed research involving intentional exposure of humans to a pesticide, EPA shall thoroughly review the material submitted under Sec. 26.1303, if any, and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

(b) EPA shall submit its review of data from human research covered by subpart Q, together with the available supporting materials, to the Human Studies Review Board if EPA decides to rely on the data and:

(1) The data are derived from research initiated after April 7, 2006, or

(2) The data are derived from research initiated before April 7, 2006, and the research was conducted for the purpose of identifying or measuring a toxic effect.

(c) In its discretion, EPA may submit data from research not covered by paragraph (b) of this section to the Human Studies Review Board for their review.

(d) EPA shall provide the submitter of the research copies of the EPA and Human Studies Review Board reviews.

§ 26.1605 Operation of the Human Studies Review Board.

EPA shall establish and operate a Human Studies Review Board as follows:

(a) Membership. The Human Studies Review Board shall consist of members who are not employed by EPA, who meet the ethics and other requirements for special government employees, and who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology.

(b) Responsibilities. The Human Studies Review Board shall comment on the scientific and ethical aspects of research proposals and reports of completed research with human subjects submitted by EPA for its review and, on request, advise EPA on ways to strengthen its programs for protection of human subjects of research.

§ 26.1606 Human Studies Review Board review of proposed human research.

In commenting on proposals for new research submitted to it by EPA, the Human Studies Review Board shall consider the scientific merits and ethical aspects of the proposed research, including all elements listed in section 26.1603(b) and (c) and any additional conditions recommended pursuant to sec. 26.1603(d).

§ 26.1607 Human Studies Review Board review of completed human research.

In commenting on reports of completed research submitted to it by EPA, the Human Studies Review Board shall consider the scientific merits and ethical aspects of the completed research, and shall apply the appropriate standards in Subpart Q.

Subpart Q: Ethical Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

§ 26.1701 To what does this subpart apply?

This subpart applies to EPA's decisions whether to rely, in actions taken under any regulatory statute it administers, on scientifically valid and relevant data from research involving intentional exposure of human subjects to a pesticide.

§ 26.1702 Definitions.

The definitions in Sec. 26.1102 and Sec. 26.1202 shall apply to this subpart as well.

§ 26.1703 Prohibitions

(a) Prohibition of reliance on scientifically invalid research involving intentional exposure of a human subject to a pesticide.

EPA shall not rely on data from research involving intentional exposure of a human subject to a pesticide unless EPA determines that the data were derived in a manner that makes them scientifically reliable and that it is appropriate to use the data for the purpose proposed by EPA. In making such determinations, EPA shall consider:

(1) Whether the proposed research was designed in accordance with scientific standards and practices prevailing at the time the research was conducted;

(2) The extent to which the research subjects are representative of the populations for the endpoint or endpoints in question; and

(3) The statistical power of the data to support the scientific conclusion EPA intends to draw from the data

(4) In a study that reports only a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), whether a dose level in the study gave rise to a biological effect, thereby demonstrating that the study had adequate sensitivity to detect an effect of interest.

(b) Prohibition of reliance on research involving intentional exposure to a pesticide of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children.

Except as provided in Sec. 26.1706, EPA shall not rely on data from any research involving intentional exposure to a pesticide of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults not subject to subparts A through L.

Except as provided in Sec. 26.1706, EPA shall not rely on data from any research involving intentional exposure of any human subject to a pesticide, where that research was not covered by subparts A through L, if there is clear and convincing evidence that the conduct of the research was fundamentally unethical (e.g., the research was intended to seriously harm participants or failed to obtain informed consent), or was deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. This prohibition is in addition to the prohibitions in Sec. 26.1703.

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults subject to subparts A through L.

Except as provided in Sec. 26.1706, EPA shall not rely on data from any research that was subject to subparts A through L at the time the research was initiated unless EPA has adequate information to determine that the research was conducted in substantial compliance with all applicable provisions of subparts A through L of this part, or if conducted in a foreign country, under procedures at least as protective as those in subparts A through L of this part. This prohibition is in addition to the prohibitions in Sec. 26.1703.

§ 26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

This section establishes the exclusive criteria and procedure by which EPA may decide to rely on data from research that is not acceptable under the standards in §§ 26.1703 through 26.1705. EPA may rely on such data only if all the conditions in paragraphs (a) through (d) of this section are satisfied:

(a) EPA has obtained the views of the Human Studies Review Board concerning the proposal to rely on the otherwise unacceptable data,

(b) EPA has provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data,

(c) EPA has determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health, such as a limitation on the use of a pesticide, than could be justified without relying on the data, and

(d) EPA publishes a full explanation of its decision to rely on the otherwise unacceptable data, including a thorough discussion of the scientific and ethical deficiencies of the underlying research and the full rationale for finding that the standard in paragraph (c) of this section was met.

CarolAnn Siciliano/DC/USEPA/US
01/03/2008 02:03 PM

To Lee Tyner
cc
bcc
Subject Re: Hearing scheduled for human studies case

Thanks for cc'ing me, Lee.

Carol Ann Siciliano
Office of General Counsel
(202) 564-5489

Lee Tyner/DC/USEPA/US

Lee Tyner/DC/USEPA/US
01/03/2008 11:03 AM

To Angela Huskey/DC/USEPA/US@EPA
cc CarolAnn Siciliano/DC/USEPA/US@EPA
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Thank you. Will there be a moot court?
Angela Huskey/DC/USEPA/US

Angela Huskey/DC/USEPA/US
01/03/2008 10:53 AM

To William Jordan/DC/USEPA/US@EPA, John Carley/DC/USEPA/US@EPA
cc Lee Tyner/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA
Subject Hearing scheduled for human studies case

I have attached the notice for the hearing in the human studies rule case. It is scheduled for January 17 in the Second Circuit Court of Appeals in NYC. Each side gets eight minutes to present its argument.

Notice of Hearing Date.pdf
****

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Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Room 7426HH - Ariel Rios North
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UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
THURGOOD MARSHALL U.S. COURT HOUSE
40 FOLEY SQUARE, NEW YORK, N.Y. 10007

Catherine O`Hagan Wolfe
CLERK OF COURT

Date: 12/7/07 Docket **06-0820-ag**
Short Title: Natural Resources Defense Council v. United States
Agency Number: 40 CFR Agency: Environmental Protection Agency

NOTICE OF HEARING DATE

Date of Hearing: Thursday, January 17, 2008
Time Allotted for Oral Argument: 8 mins per side

The above referenced appeal is scheduled for oral argument on the day indicated in the **Ceremonial Courtroom (9th Floor)** , Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, Manhattan, New York City.

Court convenes promptly at 10:00 a.m. Counsel and non-incarcerated pro se litigants must be present for argument unless earlier excused. Motions to adjourn argument must be promptly made and will be granted for grave reason only.

Counsel and non-incarcerated pro se litigants presenting oral argument must register with the courtroom deputy no later than 9:30 a.m.. Please be advised that, due to the technical difficulties, we are unable to provide offsite Video Argument until further notice. It is hoped that we will again be able to offer this convenience in the future.
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Report all settlements to the Calendar Deputy as soon as effected. Ordinarily, and subject to the ruling of the presiding judge, motions or stipulations to withdraw with prejudice will be granted without appearance by counsel, but motions or stipulations to withdraw without prejudice filed within three business days of the argument will be considered at the time of argument, with counsel present and prepared to argue the merits.

CATHERINE O`HAGAN WOLFE, Clerk

Complete Items below and return copy of entire form to the Clerk`s Office

Name of the Attorney/Pro Se Presenting argument:
Firm Name (IF APPLICABLE):
Current Telephone Number:
The above named Attorney Represents:
( ) APPELLANT-PETITIONER ( ) INTERVENOR
( ) APPELLEE-RESPONDENT ( ) AMICUS CURIAE

Date: _____ Signature: _____

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
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40 FOLEY SQUARE, NEW YORK, N.Y. 10007

Catherine O'Hagan Wolfe
CLERK OF COURT

NOTICE TO THE BAR

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Audio Tape of Argument. An audio tape of an argument may be purchased for $26 per tape by written request to the Clerk. The request should include the case name, the docket number and the date or oral argument. Tapes will be delivered by first class mail unless the request instructs to hold for pick-up or requests Federal Express Service, in which case a Federal Express account number and envelope must be provided.

Court Reporters. Parties may arrange - at their own expense - for an official court reporter to transcribe argument from a copy of the hearing tape or to attend and transcribe the hearing directly. A party must first obtain written consent from opposing counsel - or move the Court for permission - to have the court reporter attend and transcribe the hearing and must provide the calendar clerk written notice, including the name, address and telephone number of the attending reporter and, if applicable, the reporting firm at least one week prior to the hearing date.

An original and three (3) copies of the transcript **must** be submitted to the Clerk for approval by the panel that heard the case; transcripts will not be officially filed until approved.

Interpreter Services for the Hearing Impaired. Counsel requiring sign interpreters or other hearing aids must submit a written request to the Calendar Team at least two weeks before oral argument.

Jonathan Fleuchaus/DC/USEPA/US

11/29/2010 03:21 PM

To Angela Hofmann

cc Angela Huskey, Kelly Sherman

bcc

Subject OMB Request for 2d Amended Settlement Agreement in Human Studies Case

DOJ informed me that they received a request for the settlement agreement in this case from OMB. The specific requestor is Kirsten (sp?) Kim. DOJ would like us to provde the document. I have attached it. Are you the proper person to forward it to OMB?

Settlement Agreement 2d executed.pdf

SECOND AMENDED SETTLEMENT AGREEMENT

This Second Amended Settlement Agreement is entered into by and among Petitioners Natural Resources Defense Council, Inc., Pesticide Action Network North America, Pineros y Campesinos Unidos Del Noroeste, Physicians for Social Responsibility - San Francisco, Farm Labor Organizing Committee, AFL-CIO, and Migrant Clinicians Network (collectively "Petitioners") and the U.S. Environmental Protection Agency ("EPA") and supersedes the Settlement Agreement executed by Petitioners on May 18, 2010 and by EPA on June 16, 2010, and supersedes the Amended Settlement Agreement executed by Petitioners on August 2 and 6, 2010 and by EPA on August 16, 2010.

WHEREAS, on February 6, 2006, EPA published in the Federal Register a final rule entitled "Protections for Subjects in Human Research." *See* 71 Fed. Reg. 6138 (Feb. 6, 2006) (the "2006 final rule");

WHEREAS, the Petitioners filed four petitions for review of the 2006 final rule, which were consolidated in the United States Court of Appeals for the Second Circuit, Case Nos. 06-0820-ag, 06-1895-ag, 06-2149-ag, 06-2360-ag (2nd Cir.);

WHEREAS, the Petitioners also filed a complaint seeking judicial review of the 2006 final rule in the United States District Court for the Northern District of California, Case No. 06-01366.

WHEREAS, the Parties wish to settle the Petitioners' challenges to the 2006 final rule ;

WHEREAS, settlement of the Petitioners' challenges to the 2006 final rule is in the public interest;

NOW, THEREFORE, without admission of any issues of fact or law, or waiver of any claim or defense, either factual or legal, the Parties agree as follows:

Specific Provisions

1. EPA agrees to conduct notice-and-comment rulemaking in accordance with the Administrative Procedure Act on the issue of whether the 2006 final rule should be amended.

2. No later than January 18, 2011, EPA agrees to sign a notice of proposed rulemaking that proposes, at a minimum, the amendments to the 2006 final rule as substantially consistent with Exhibit A. After considering any public comments received, EPA agrees to take final action on the proposed rule, which may include signing a notice of final rulemaking. EPA will take such final action no later than December 18, 2011.

Procedural Matters

3. No later than 15 days after execution of this Settlement Agreement by the parties, Petitioners shall move to dismiss with prejudice Case No. 06-01366 pending in the United States District Court for the Northern District of California.

4. Petitioners agree not to seek further judicial review of the 2006 final rule in the United States Court of Appeals for the Second Circuit or in any other United States Court of Appeals.

Petitioners' Remedies

5. The parties agree that there is no available judicial remedy if EPA fails to take the actions described in paragraph 2, by the schedule contained in paragraph 2.

6. Any challenge to any amendments to the 2006 final rule must be brought in a new action, and Petitioners reserve whatever rights they may have to bring such a challenge, except as specifically provided below. Notwithstanding the foregoing sentence, if EPA amends the 2006 final rule by adopting the language of Exhibit A without making any material changes to the language of Exhibit A, Petitioners will not exercise whatever rights they may have to seek judicial review of those amendments pursuant to 21 U.S.C. § 346a(h)(1) or otherwise. Nothing in this Amended Settlement Agreement shall restrict Petitioners' rights to comment on or otherwise participate in the APA rulemaking discussed in paragraph 1.

General Provisions

7. Nothing in the terms of this Second Amended Settlement Agreement shall be construed to limit or modify the discretion accorded EPA by the Department of the Interior, Environment and Related Agencies Appropriations Act, 2006; the Federal Food, Drug, and Cosmetic Act; the Federal Insecticide, Fungicide and Rodenticide Act; or general principles of administrative law.

8. Nothing in this Second Amended Settlement Agreement shall be construed to limit or modify EPA's discretion to alter, amend, or revise 40 C.F.R. Parts 26 and 150 through 180, or to promulgate superseding rules or subsequent guidance. Nothing in this Second Amended Settlement Agreement shall be construed to limit or modify EPA's discretion to propose additional regulatory changes in the same notice of

proposed rulemaking signed pursuant to paragraph 2 and to finalize additional or different regulatory changes in the same notice of final rulemaking signed pursuant to paragraph 2.

9. Until any amendments to the 2006 final rule become effective, the 2006 final rule remains in effect.

10. This is the entire Second Amended Settlement Agreement between the Parties with respect to the Petitioners' petitions for review of the 2006 final rule. All prior conversations, meetings, discussions, drafts, and writings of any kind are specifically superseded by this Second Amended Settlement Agreement and may not be used by the Parties to vary or contest the terms of this Second Amended Settlement Agreement, or as evidence of the Parties' intent in entering into this Second Amended Settlement Agreement.

11. The Parties may agree in writing to modify any provision of this Second Amended Settlement Agreement.

12. Nothing in this Second Amended Settlement Agreement shall be construed to constitute an admission of any issue of fact, law, or liability by any of the Parties. Except as expressly provided in this Second Amended Settlement Agreement, none of the Parties waives or relinquishes any legal rights, claims, or defenses it may have.

13. EPA agrees to pay Petitioners $ 135,000 in full satisfaction of Petitioners' claims for attorney fees and costs in this litigation.

14. The undersigned representatives of each Party certify that they are fully authorized by the Party or Parties they represent to bind the respective Parties to the terms of this Second Amended Settlement Agreement. This Second Amended Settlement Agreement may be signed in counterparts, which, taken together, shall constitute the whole. This Second Amended Settlement Agreement will be deemed to be executed and shall become effective when it has been signed by all of the representatives of the Parties set forth below.

15. No provision of this Second Amended Settlement Agreement shall be interpreted as or constitute a commitment or requirement that EPA obligate or pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. § 1341, or take actions in contravention of the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706, or any other law or regulation, either substantive or procedural.

16. It is hereby expressly understood and agreed that this Second Amended Settlement Agreement was jointly drafted by the Parties. Accordingly, the Parties hereby agree that any and all rules of construction to the effect that ambiguity is construed against the drafting party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Second Amended Settlement Agreement.

17. Circumstances that are not reasonably foreseeable and that are outside the reasonable control of EPA could possibly delay compliance with the schedule established in paragraphs 2. Such situations include, but are not limited to, a government shut-down such as occurred in 1995 and 1996, or catastrophic environmental events requiring immediate and/or time-consuming response by EPA.

Should a delay occur due to such circumstances, any resulting failure to meet the timetables set forth herein shall not constitute a failure to comply with the terms of this Second Amended Settlement Agreement, and any deadlines shall be extended one day for each day of the delay. EPA will provide the Petitioners with notice as soon as is reasonably possible under the circumstances in the event that EPA invokes this term of the Second Amended Settlement Agreement and will provide Petitioners with an explanation of EPA's basis for invoking the provisions of this Paragraph.

COUNSEL FOR PETITIONERS NATURAL RESOURCES DEFENSE COUNCIL, PHYSICIANS FOR SOCIAL RESPONSIBILITY - SAN FRANCISCO, FARM LABOR ORGANIZING COMMITTEE, AFL-CIO, AND MIGRANT CLINICIANS NETWORK:

Date: 15 OCT 2010

Michael E. Wall
Natural Resources Defense Council
111 Sutter Street, 20th Floor
San Francisco, CA 94104
(415) 875-6100

COUNSEL FOR PETITIONERS PESTICIDE ACTION NETWORK NORTH AMERICA AND PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE

Date: Oct. 14, 2010

Jan Hasselman
Earthjustice
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Seattle, WA 98104
(206) 343-7340

COUNSEL FOR RESPONDENT EPA:

IGNACIA S. MORENO
Assistant Attorney General
Environment and Natural Resources Division
U.S. Department of Justice

Date: Nov 3, 2010

ALAN D. GREENBERG
Trial Attorney
Environmental Defense Section
U.S. Department of Justice
999 18th Street
South Terrace, Suite 370
Denver, Colorado 80294
(303) 844-1366

Kelly Sherman/DC/USEPA/US
11/29/2010 03:40 PM

To William Jordan, Laura Parsons
cc
bcc
Subject Fw: OMB Request for 2d Amended Settlement Agreement in Human Studies Case

fyi

Kelly Sherman
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-8401
----- Forwarded by Kelly Sherman/DC/USEPA/US on 11/29/2010 03:40 PM -----

From: Jonathan Fleuchaus/DC/USEPA/US
To: Angela Hofmann/DC/USEPA/US@EPA
Cc: Angela Huskey/DC/USEPA/US@EPA, Kelly Sherman/DC/USEPA/US@EPA
Date: 11/29/2010 03:21 PM
Subject: OMB Request for 2d Amended Settlement Agreement in Human Studies Case

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Settlement Agreement 2d executed.pdf

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WHEREAS, settlement of the Petitioners' challenges to the 2006 final rule is in the public interest;

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5. The parties agree that there is no available judicial remedy if EPA fails to take the actions described in paragraph 2, by the schedule contained in paragraph 2.

6. Any challenge to any amendments to the 2006 final rule must be brought in a new action, and Petitioners reserve whatever rights they may have to bring such a challenge, except as specifically provided below. Notwithstanding the foregoing sentence, if EPA amends the 2006 final rule by adopting the language of Exhibit A without making any material changes to the language of Exhibit A, Petitioners will not exercise whatever rights they may have to seek judicial review of those amendments pursuant to 21 U.S.C. § 346a(h)(1) or otherwise. Nothing in this Amended Settlement Agreement shall restrict Petitioners' rights to comment on or otherwise participate in the APA rulemaking discussed in paragraph 1.

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COUNSEL FOR PETITIONERS NATURAL RESOURCES DEFENSE COUNCIL, PHYSICIANS FOR SOCIAL RESPONSIBILITY - SAN FRANCISCO, FARM LABOR ORGANIZING COMMITTEE, AFL-CIO, AND MIGRANT CLINICIANS NETWORK:

Date: 15 OCT 2010

Michael E. Wall
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111 Sutter Street, 20th Floor
San Francisco, CA 94104
(415) 875-6100

COUNSEL FOR PETITIONERS PESTICIDE ACTION NETWORK NORTH AMERICA AND PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE

Date: Oct. 14, 2010

Jan Hasselman
Earthjustice
705 Second Ave., Suite 203
Seattle, WA 98104
(206) 343-7340

COUNSEL FOR RESPONDENT EPA:

IGNACIA S. MORENO
Assistant Attorney General
Environment and Natural Resources Division
U.S. Department of Justice

Date: Nov 3, 2010

ALAN D. GREENBERG
Trial Attorney
Environmental Defense Section
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999 18th Street
South Terrace, Suite 370
Denver, Colorado 80294
(303) 844-1366

Lee Tyner/DC/USEPA/US
01/03/2008 11:03 AM

To Angela Huskey
cc CarolAnn Siciliano
bcc
Subject Re: Hearing scheduled for human studies case

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Angela M.D. Huskey
Office of General Counsel, Pesticides and Toxic Substances Law Office
Mail Code 2333A
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Room 7426HH - Ariel Rios North
Phone: (202) 564-2892
Fax: (202) 564-5644

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
THURGOOD MARSHALL U.S. COURT HOUSE
40 FOLEY SQUARE, NEW YORK, N.Y. 10007

Catherine O`Hagan Wolfe
CLERK OF COURT

Date: 12/7/07 Docket **06-0820-ag**
Short Title: Natural Resources Defense Council v. United States
Agency Number: 40 CFR Agency: Environmental Protection Agency

NOTICE OF HEARING DATE

Date of Hearing: Thursday, January 17, 2008
Time Allotted for Oral Argument: 8 mins per side

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CATHERINE O`HAGAN WOLFE, Clerk

Complete Items below and return copy of entire form to the Clerk`s Office

Name of the Attorney/Pro Se Presenting argument:
Firm Name (IF APPLICABLE):
Current Telephone Number:
The above named Attorney Represents:
( ) APPELLANT-PETITIONER ( ) INTERVENOR
( ) APPELLEE-RESPONDENT ( ) AMICUS CURIAE

Date: _____ Signature: _____

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
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Lee Tyner/DC/USEPA/US
01/03/2008 11:42 AM

To Roger Cortesi
cc
bcc
Subject Fw: Hearing scheduled for human studies case

FYI
----- Forwarded by Lee Tyner/DC/USEPA/US on 01/03/2008 11:42 AM -----

Lee Tyner/DC/USEPA/US
01/03/2008 11:03 AM

To Angela Huskey/DC/USEPA/US
cc CarolAnn Siciliano/DC/USEPA/US@EPA
Subject Re: Hearing scheduled for human studies case

Thank you. Will there be a moot court?
Angela Huskey/DC/USEPA/US

Angela Huskey/DC/USEPA/US
01/03/2008 10:53 AM

To William Jordan/DC/USEPA/US@EPA, John Carley/DC/USEPA/US@EPA
cc Lee Tyner/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA
Subject Hearing scheduled for human studies case

I have attached the notice for the hearing in the human studies rule case. It is scheduled for January 17 in the Second Circuit Court of Appeals in NYC. Each side gets eight minutes to present its argument.


Notice of Hearing Date.pdf
****

Angela M.D. Huskey
Office of General Counsel, Pesticides and Toxic Substances Law Office
Mail Code 2333A
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Room 7426HH - Ariel Rios North
Phone: (202) 564-2892
Fax: (202) 564-5644

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
THURGOOD MARSHALL U.S. COURT HOUSE
40 FOLEY SQUARE, NEW YORK, N.Y. 10007

Catherine O`Hagan Wolfe
CLERK OF COURT

Date: 12/7/07 Docket **06-0820-ag**
Short Title: Natural Resources Defense Council v. United States
Agency Number: 40 CFR Agency: Environmental Protection Agency

NOTICE OF HEARING DATE

Date of Hearing: Thursday, January 17, 2008
Time Allotted for Oral Argument: 8 mins per side

The above referenced appeal is scheduled for oral argument on the day indicated in the **Ceremonial Courtroom (9th Floor)** , Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, Manhattan, New York City.

Court convenes promptly at 10:00 a.m. Counsel and non-incarcerated pro se litigants must be present for argument unless earlier excused. Motions to adjourn argument must be promptly made and will be granted for grave reason only.

Counsel and non-incarcerated pro se litigants presenting oral argument must register with the courtroom deputy no later than 9:30 a.m.. Please be advised that, due to the technical difficulties, we are unable to provide offsite Video Argument until further notice. It is hoped that we will again be able to offer this convenience in the future.
Counsel and non-incarcerated pro se litigants may seek the Court`s permission to waive oral argument by submitting a letter request to the Office of Clerk (attention Calendar Deputy) not later than five days before the hearing week.

Report all settlements to the Calendar Deputy as soon as effected. Ordinarily, and subject to the ruling of the presiding judge, motions or stipulations to withdraw with prejudice will be granted without appearance by counsel, but motions or stipulations to withdraw without prejudice filed within three business days of the argument will be considered at the time of argument, with counsel present and prepared to argue the merits.

CATHERINE O`HAGAN WOLFE, Clerk

Complete Items below and return copy of entire form to the Clerk`s Office

Name of the Attorney/Pro Se Presenting argument:
Firm Name (IF APPLICABLE):
Current Telephone Number:
The above named Attorney Represents:
( ) APPELLANT-PETITIONER ( ) INTERVENOR
( ) APPELLEE-RESPONDENT ( ) AMICUS CURIAE

Date: _____ Signature: _____

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William Jordan/DC/USEPA/US
01/03/2008 11:41 AM

To Angela Huskey
cc John Carley, Lee Tyner, Philip Ross
bcc
Subject Re: Hearing scheduled for human studies case

Thanks. Will there be a moot court? If so, I would like to attend.

Thanks,

Bill

William L. Jordan
Senior Policy Adviser
Office of Pesticide Programs -- Mail code 7501P
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
(703) 305-1049 (voice)
(703) 308-4776 (fax)
Angela Huskey/DC/USEPA/US

Angela Huskey/DC/USEPA/US
01/03/2008 10:53 AM

To William Jordan/DC/USEPA/US@EPA, John Carley/DC/USEPA/US@EPA
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